

COVID-19 mRNA Pfizer - BioNTech vaccine analysis print

All UK spontaneous reports received between 9/12/20 and 03/11/21 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: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Anaemia folate deficiency	1	0
Anaemia vitamin B12 deficiency	3	0
Deficiency anaemia	1	0
Iron deficiency anaemia	8	0
<i>Anaemias NEC</i>		
Anaemia	108	0
Anaemia macrocytic	2	0
Anaemia megaloblastic	1	0
Autoimmune anaemia	3	0
Blood loss anaemia	1	0
Microcytic anaemia	1	0
<i>Anaemias haemolytic NEC</i>		
Coombs negative haemolytic anaemia	1	0
Haemolytic anaemia	7	0
<i>Anaemias haemolytic immune</i>		
Autoimmune haemolytic anaemia	14	0
Evans syndrome	1	0
Warm type haemolytic anaemia	1	0
<i>Anaemias haemolytic mechanical factor</i>		
Microangiopathic haemolytic anaemia	1	0
<i>Bleeding tendencies</i>		
Haemorrhagic diathesis	1	0
Increased tendency to bruise	44	0
Spontaneous haematoma	2	0
<i>Coagulation factor deficiencies</i>		
Acquired haemophilia	2	0
<i>Coagulopathies</i>		
Abnormal clotting factor	4	0
Antiphospholipid syndrome	5	0
Coagulopathy	24	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	7	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	9	0
<i>Leukopenias NEC</i>		
Leukopenia	4	1
Lymphopenia	4	0
<i>Lymphatic system disorders NEC</i>		

Case Series Drug Analysis Print

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Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Blood disorders Blood disorders cont'd		
Abdominal lymphadenopathy	3	0
Hilar lymphadenopathy	2	0
Lymph node pain	1589	0
Lymph node ulcer	1	0
Lymphadenitis	134	0
Lymphadenopathy	10010	0
Lymphatic disorder	1	0
Lymphatic insufficiency	1	0
Necrotic lymphadenopathy	3	0
Pseudolymphoma	11	0
Retroperitoneal lymphadenopathy	1	0
<i>Marrow depression and hypoplastic anaemias</i>		
Aplasia pure red cell	2	0
Hypoplastic anaemia	2	0
Myelosuppression	1	0
Pancytopenia	7	0
<i>Neutropenias</i>		
Autoimmune neutropenia	2	0
Neutropenia	37	0
<i>Platelet disorders NEC</i>		
Platelet anisocytosis	1	0
Platelet disorder	4	0
<i>Polycythaemia (excl rubra vera)</i>		
Polycythaemia	3	0
<i>Purpuras (excl thrombocytopenic)</i>		
Purpura non-thrombocytopenic	1	0
<i>Red blood cell abnormal findings NEC</i>		
Macrocytosis	1	0
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	11	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	73	0
Thrombocytopenia	200	1
Thrombocytopenic purpura	6	0
Thrombotic thrombocytopenic purpura	6	0
<i>Thrombocytoses</i>		
Thrombocytosis	6	0
Blood disorders SOC TOTAL	12427	3

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Data Lock Date: 03-Nov-2021 18:30:04

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Aortic valvular disorders</i>		
Aortic valve incompetence	1	0
<i>Cardiac conduction disorders</i>		
Atrioventricular block	14	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 left	2	0
Bundle branch block right	1	0
<i>Cardiac disorders NEC</i>		
Acute cardiac event	3	0
Cardiac disorder	52	0
Cardiac dysfunction	1	0
Cardiovascular deconditioning	1	0
Cardiovascular disorder	5	0
Intracardiac thrombus	6	0
<i>Cardiac hypertensive complications</i>		
Hypertensive heart disease	1	0
<i>Cardiac infections and inflammations NEC</i>		
Carditis	2	0
<i>Cardiac neoplasms NEC</i>		
Pericardial cyst	1	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	18	0
Cardiovascular symptom	1	0
Palpitations	3226	1
<i>Cardiac valve disorders NEC</i>		
Cardiac valve disease	2	0
Heart valve incompetence	2	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	4	0
Congestive cardiomyopathy	6	0
Stress cardiomyopathy	2	0
<i>Coronary artery disorders NEC</i>		
Coronary artery disease	6	3
Coronary artery occlusion	2	0
Coronary artery thrombosis	2	1
<i>Endocarditis NEC</i>		
Endocarditis noninfective	1	1
<i>Heart failures NEC</i>		
Cardiac failure	65	8
Cardiac failure acute	5	1
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	20	1
Angina pectoris	184	1
Angina unstable	2	0
Arteriospasm coronary	3	0

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Data Lock Date: 03-Nov-2021 18:30:04

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Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Microvascular coronary artery disease	2	0
Myocardial infarction	195	33
Myocardial ischaemia	8	4
Left ventricular failures		
Acute left ventricular failure	1	1
Left ventricular failure	7	2
Mitral valvular disorders		
Mitral valve incompetence	6	0
Mitral valve prolapse	1	0
Myocardial disorders NEC		
Cardiac amyloidosis	1	0
Cardiac aneurysm	1	1
Cardiomegaly	27	2
Left atrial dilatation	1	0
Left ventricular dysfunction	9	0
Left ventricular enlargement	1	0
Left ventricular hypertrophy	2	0
Myocardial fibrosis	4	0
Myocardial haemorrhage	1	0
Myocardial injury	10	0
Myocardial oedema	4	0
Myocardial rupture	1	0
Right ventricular enlargement	1	0
Ventricular hypertrophy	1	0
Noninfectious myocarditis		
Myocarditis	400	1
Noninfectious pericarditis		
Pericarditis	304	1
Pericardial disorders NEC		
Pericardial effusion	31	0
Pericardial fibrosis	1	0
Pericardial haemorrhage	3	3
Pericardial rub	2	0
Rate and rhythm disorders NEC		
Arrhythmia	123	0
Bradycardia	56	0
Bradycardia foetal	2	1
Cardiac flutter	391	0
Extrasystoles	141	0
Heart alternation	1	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	19	0
Tachyarrhythmia	3	0
Tachycardia	810	0
Tachycardia foetal	1	0
Tachycardia paroxysmal	1	0
Right ventricular failures		
Cor pulmonale	1	0
Supraventricular arrhythmias		
Arrhythmia supraventricular	11	0
Atrial fibrillation	177	0
Atrial flutter	23	0
Atrial tachycardia	9	0

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Cardiac disorders Cardiac disorders cont'd		
Nodal arrhythmia	1	0
Sinus arrest	1	0
Sinus arrhythmia	4	0
Sinus bradycardia	10	0
Sinus node dysfunction	1	0
Sinus tachycardia	53	0
Supraventricular extrasystoles	2	0
Supraventricular tachycardia	37	0
<i>Tricuspid valvular disorders</i>		
Tricuspid valve incompetence	4	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	94	38
Cardio-respiratory arrest	1	1
Pulseless electrical activity	4	0
Ventricular arrhythmia	5	0
Ventricular extrasystoles	23	0
Ventricular fibrillation	6	1
Ventricular tachycardia	12	0
Cardiac disorders SOC TOTAL	6714	111

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Autosomal chromosomal abnormalities</i>		
Trisomy 8	1	0
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	12	0
<i>Cardiac hypoplasias congenital</i>		
Ventricular hypoplasia	1	0
<i>Cardiac septal defects congenital</i>		
Atrial septal defect	2	0
Hypertrophic cardiomyopathy	1	0
Ventricular septal defect	1	0
<i>Cardiac valve disorders congenital</i>		
Bicuspid aortic valve	2	0
<i>Central nervous system disorders congenital NEC</i>		
Spina bifida	1	0
Syringomyelia	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	3	0
<i>Coagulation disorders congenital</i>		
Haemophilia	2	0
<i>Congenital disorders NEC</i>		
Foetal malformation	1	0
Heterotaxia	1	0
Young's syndrome	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	2	0
<i>Gastrointestinal tract disorders congenital NEC</i>		
Gastroschisis	2	0
<i>Great vessel disorders congenital</i>		
Congenital great vessel anomaly	1	0
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>Inborn errors of metabolism NEC</i>		
Alpha-1 antitrypsin deficiency	1	0
<i>Inborn errors of porphyrin metabolism</i>		
Porphyria	1	0
<i>Lymphatic system disorders congenital</i>		
Cystic lymphangioma	3	0
<i>Male reproductive tract disorders congenital</i>		
Cryptorchism	1	0
Micropenis	3	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>		
Block vertebra	1	0

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Reaction Name	Total	Fatal
Congenital disorders Congenital disorders cont'd		
Brachyolmia	1	0
Neurological disorders congenital NEC		
Familial hemiplegic migraine	2	0
Familial periodic paralysis	1	0
Moebius II syndrome	1	0
Tourette's disorder	2	0
Ocular disorders congenital NEC		
Colour blindness	4	0
Congenital eye disorder	1	0
Palate disorders congenital		
Cleft lip and palate	2	0
Peripheral nervous system disorders congenital NEC		
Hereditary neuropathy with liability to pressure palsies	1	0
Paroxysmal extreme pain disorder	1	0
Pulmonary and bronchial disorders congenital		
Congenital cystic lung	1	0
Retinal disorders congenital		
Retinitis pigmentosa	1	0
Sex chromosomal abnormalities		
Turner's syndrome	1	0
Skin and subcutaneous tissue disorders congenital NEC		
Acral peeling skin syndrome	1	0
Tongue disorders congenital		
Ankyloglossia congenital	1	0
Venous disorders congenital		
Anomalous pulmonary venous connection	1	0
Congenital disorders SOC TOTAL	77	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear canal erythema	1	0
Ear congestion	29	0
Ear discomfort	89	0
Ear disorder	15	0
Ear haemorrhage	9	0
Ear pain	901	0
Ear pruritus	9	0
Ear swelling	33	0
Otorrhoea	4	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	2	0
Excessive cerumen production	8	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	6	0
Diplacusis	2	0
<i>Hearing losses</i>		
Conductive deafness	1	0
Deafness	222	0
Deafness bilateral	7	0
Deafness neurosensory	17	0
Deafness transitory	6	0
Deafness unilateral	30	0
Hypoacusis	167	0
Sudden hearing loss	44	0
<i>Hyperacusia</i>		
Hyperacusis	52	0
Misophonia	3	0
<i>Inner ear disorders NEC</i>		
Acute vestibular syndrome	2	0
Inner ear disorder	12	0
Meniere's disease	11	0
Vestibular disorder	10	0
<i>Inner ear infections and inflammations</i>		
Inner ear inflammation	8	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	56	0
Tinnitus	1805	0
Vertigo	1294	0
Vertigo labyrinthine	10	0
Vertigo positional	69	0
<i>Mastoid disorders</i>		
Mastoid effusion	1	0
<i>Middle ear disorders NEC</i>		
Middle ear disorder	3	0

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MedDRA Version: MedDRA 24.1

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	4965	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	2	0
Thyroiditis	17	0
Thyroiditis acute	2	0
Thyroiditis subacute	3	0
<i>Adrenal cortical hypofunctions</i>		
Addison's disease	2	0
Adrenal insufficiency	2	0
Adrenocortical insufficiency acute	13	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	4	0
Premature menarche	17	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	46	0
Ovulation delayed	32	0
<i>Male gonadal function disorders</i>		
Androgen deficiency	1	0
<i>Thyroid disorders NEC</i>		
Autoimmune thyroid disorder	1	0
Goitre	12	0
Thyroid disorder	7	0
Thyroid mass	1	0
Thyroid pain	7	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	8	0
Hyperthyroidism	33	0
Thyrotoxic crisis	3	0
<i>Thyroid hypofunction disorders</i>		
Autoimmune hypothyroidism	1	0
Hypothyroidism	30	0
Immune-mediated hypothyroidism	1	0
Myxoedema	1	0
Endocrine disorders SOC TOTAL	251	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	6	0
<i>Cataract conditions</i>		
Cataract	11	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	5	0
Vitreous detachment	17	0
Vitreous floaters	84	0
<i>Colour blindness (incl acquired)</i>		
Dyschromatopsia	8	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	40	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	2	0
Keratitis	6	0
Ulcerative keratitis	5	0
<i>Eyelid movement disorders</i>		
Blepharospasm	137	0
Excessive eye blinking	5	0
Eyelid function disorder	3	0
Eyelid myokymia	4	0
Eyelid ptosis	42	0
Paralytic lagophthalmos	2	0
<i>Glaucomas (excl congenital)</i>		
Angle closure glaucoma	2	0
Glaucoma	6	0
<i>Iris and ciliary body structural change, deposit and degeneration</i>		
Eye colour change	3	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Autoimmune uveitis	1	0
Iridocyclitis	14	0
Iritis	7	0
Uveitis	43	0
<i>Lacrimation disorders</i>		
Dry eye	136	0
Lacrimation increased	123	0
<i>Lid bleeding and vascular disorders</i>		
Eyelid bleeding	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Blepharitis	14	0
Chalazion	7	0
Eczema eyelids	7	0
Erythema of eyelid	9	0
Eyelid cyst	4	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Eyelid irritation	2	0
Eyelid margin crusting	4	0
Eyelid oedema	5	0
Eyelid rash	16	0
Swelling of eyelid	112	0
Swollen tear duct	2	0
Lid, lash and lacrimal structural disorders		
Dacryostenosis acquired	1	0
Dermatochalasis	1	0
Eyelash changes	1	0
Eyelid exfoliation	3	0
Eyelid skin dryness	2	0
Eyelid thickening	1	0
Floppy eyelid syndrome	1	0
Growth of eyelashes	3	0
Lagophthalmos	3	0
Ocular bleeding and vascular disorders NEC		
Eye haematoma	4	0
Eye haemorrhage	27	0
Ocular vascular disorder	2	0
Ophthalmic vein thrombosis	1	0
Ocular disorders NEC		
Dark circles under eyes	6	0
Eye disorder	32	0
Eye oedema	15	0
Eye pain	983	0
Eye swelling	470	0
Eye symptom	9	0
Eye ulcer	3	0
Eyelid disorder	12	0
Eyelid pain	11	0
Eyelids pruritus	6	0
Ocular discomfort	25	0
Periorbital oedema	18	0
Periorbital pain	1	0
Periorbital swelling	114	0
Retinal disorder	2	0
Vitreous disorder	1	0
Ocular infections, inflammations and associated manifestations		
Eye allergy	12	0
Eye discharge	25	0
Eye inflammation	25	0
Eye irritation	83	0
Eye pruritus	219	0
Limbal swelling	2	0
Ocular hyperaemia	205	0
Ocular nerve and muscle disorders		
Binocular eye movement disorder	1	0
Extraocular muscle disorder	1	0
Extraocular muscle paresis	2	0
Eye movement disorder	31	0
Gaze palsy	1	0
Ocular myasthenia	1	0

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Eye disorders Eye disorders cont'd		
Ophthalmoplegia	4	0
Strabismus	5	0
Ocular sensation disorders		
Abnormal sensation in eye	18	0
Asthenopia	141	0
Eye paraesthesia	2	0
Eyelid sensory disorder	1	0
Foreign body sensation in eyes	16	0
Hypoaesthesia eye	15	0
Photophobia	427	0
Optic disc abnormalities NEC		
Papilloedema	6	0
Optic nerve bleeding and vascular disorders		
Optic disc haemorrhage	1	0
Optic ischaemic neuropathy	2	0
Orbital infections, inflammations and irritations		
Parophthalmia	1	0
Orbital structural change, deposit and degeneration		
Orbital oedema	2	0
Pupil disorders		
Miosis	2	0
Mydriasis	22	0
Pupil fixed	2	0
Pupils unequal	12	0
Refractive and accommodative disorders		
Accommodation disorder	1	0
Altered visual depth perception	3	0
Astigmatism	2	0
Hypermetropia	2	0
Myopia	1	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Retinal artery occlusion	9	0
Retinal artery thrombosis	1	0
Retinal haemorrhage	7	0
Retinal vascular thrombosis	1	0
Retinal vein occlusion	31	0
Retinal vein thrombosis	2	0
Retinal structural change, deposit and degeneration		
Macular degeneration	4	0
Macular hole	2	0
Macular rupture	1	0
Maculopathy	1	0
Neovascular age-related macular degeneration	2	0
Retinal degeneration	1	0
Retinal detachment	4	0
Retinal tear	2	0
Retinal toxicity	3	0
Retinal, choroid and vitreous infections and inflammations		
Birdshot chorioretinopathy	2	0
Cystoid macular oedema	1	0
Macular oedema	4	0
Retinal vasculitis	3	0
Retinopathies NEC		

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Acute macular neuroretinopathy	1	0
Retinal exudates	2	0
Retinopathy	2	0
<i>Scleral infections, irritations and inflammations</i>		
Episcleritis	7	0
Scleritis	3	0
<i>Scleral structural change, deposit and degeneration</i>		
Scleral discolouration	2	0
<i>Structural change, deposit and degeneration of eye NEC</i>		
Exophthalmos	1	0
<i>Visual colour distortions</i>		
Chloropsia	2	0
Chromatopsia	1	0
Cyanopsia	2	0
Erythropsia	2	0
Xanthopsia	1	0
<i>Visual disorders NEC</i>		
Charles Bonnet syndrome	2	0
Diplopia	147	0
Glare	1	0
Halo vision	7	0
Heteronymous diplopia	1	0
Metamorphopsia	18	0
Oscillopsia	3	0
Photopsia	122	0
Scintillating scotoma	4	0
Vision blurred	1106	0
Visual brightness	3	0
Visual snow syndrome	7	0
<i>Visual field disorders</i>		
Visual field defect	26	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Amaurosis fugax	2	0
Blindness	115	0
Blindness cortical	1	0
Blindness transient	12	0
Blindness unilateral	12	0
Central vision loss	3	0
Sudden visual loss	3	0
Visual acuity reduced	23	0
Visual acuity reduced transiently	1	0
Visual impairment	328	0
<i>Visual pathway disorders</i>		
Optic nerve disorder	1	0
Eye disorders SOC TOTAL	6016	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Abdominal mass	2	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	14	0
Pancreatitis acute	13	1
Pancreatitis necrotising	1	0
<i>Anal and rectal disorders NEC</i>		
Anal fissure	2	0
Anal sphincter atony	1	0
Rectal prolapse	1	0
<i>Anal and rectal pains</i>		
Proctalgia	11	0
<i>Anal and rectal signs and symptoms</i>		
Anal hypoaesthesia	1	0
Anal spasm	1	0
Anorectal discomfort	4	0
Anorectal swelling	1	0
Rectal discharge	2	0
Rectal tenesmus	1	0
<i>Benign oral cavity neoplasms</i>		
Mouth cyst	6	0
Tongue cyst	4	0
<i>Colitis (excl infective)</i>		
Autoimmune colitis	2	0
Colitis	40	1
Colitis ischaemic	1	0
Colitis microscopic	1	0
Colitis ulcerative	64	0
Crohn's disease	40	0
Eosinophilic colitis	1	0
Inflammatory bowel disease	5	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	1	0
<i>Dental disorders NEC</i>		
Loose tooth	1	0
Malpositioned teeth	3	0
Periodontal disease	1	0
Teeth brittle	2	0
Teething	6	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	34	0
Toothache	146	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Dental surface disorders</i>		
Tooth discolouration	9	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	6	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	4804	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	395	0
Epigastric discomfort	14	0
Eructation	45	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	19	0
Faecaloma	4	0
Faeces discoloured	56	0
Faeces hard	2	0
Faeces pale	3	0
Faeces soft	10	0
Mucous stools	10	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	481	0
Aerophagia	3	0
Flatulence	169	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	3	0
Gastritis	50	0
Reflux gastritis	5	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal migraine	2	0
Abdominal pain	1318	0
Abdominal pain lower	120	0
Abdominal pain upper	2170	0
Abdominal rigidity	22	0
Abdominal tenderness	10	0
Gastrointestinal pain	120	0
Oesophageal pain	9	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	232	0
Duodenogastric reflux	4	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Gastric dilatation	7	0
Gastroesophageal reflux disease	135	0
Impaired gastric emptying	9	0
Infrequent bowel movements	3	0
Intestinal dilatation	1	0
Intestinal pseudo-obstruction	2	0
<i>Gastrointestinal disorders NEC</i>		
Appendix disorder	1	0
Food poisoning	7	0
Functional gastrointestinal disorder	10	0
Gastric disorder	9	0
Gastrointestinal disorder	21	0
Stomach mass	4	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	6	0
Change of bowel habit	5	0
Dyschezia	2	0
Gastrointestinal motility disorder	3	0
Oesophageal achalasia	1	0
<i>Gastrointestinal fistulae</i>		
Diverticular fistula	2	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Duodenitis	1	0
Enteritis	6	0
Epiploic appendagitis	2	0
Gastrointestinal inflammation	3	0
Gastrointestinal tract irritation	1	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	547	0
Abdominal symptom	1	0
Acute abdomen	5	0
Anal incontinence	19	0
Breath odour	18	0
Dysphagia	193	1
Gastrointestinal wall thickening	1	0
Odynophagia	32	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Cardiospasm	1	0
Defaecation urgency	10	0
Frequent bowel movements	26	0
Gastrointestinal hypermotility	1	0
Irritable bowel syndrome	79	0
Oesophageal spasm	3	0
Pylorospasm	1	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intestinal obstruction	4	0
Neonatal intestinal obstruction	1	0
<i>Gastrointestinal vascular malformations</i>		
Gastric antral vascular ectasia	10	0
<i>Gastrointestinal vascular occlusion and infarction</i>		

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Intestinal ischaemia	5	2
Mesenteric vein thrombosis	6	0
Omental infarction	1	0
Thrombosis mesenteric vessel	2	0
Visceral venous thrombosis	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival blister	11	0
Gingival discomfort	6	0
Gingival disorder	3	0
Gingival erythema	2	0
Gingival hypertrophy	1	0
Gingival oedema	1	0
Gingival pain	97	0
Gingival pruritus	1	0
Gingival swelling	32	0
Gingival ulceration	1	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	8	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	59	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Gastric varices	1	0
Haemorrhoidal haemorrhage	1	0
Haemorrhoids	31	1
Haemorrhoids thrombosed	1	0
<i>Inguinal hernias</i>		
Inguinal hernia	1	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	20	1
Intestinal haemorrhage	1	0
Rectal haemorrhage	66	0
Small intestinal haemorrhage	5	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	10	0
Malabsorption	1	0
Steatorrhoea	4	0
<i>Nausea and vomiting symptoms</i>		
Discoloured vomit	12	0
Infantile vomiting	7	0
Nausea	12440	0
Regurgitation	1	0
Retching	94	0
Vomiting	3909	1
Vomiting projectile	53	0
<i>Non-mechanical ileus</i>		
Ileus paralytic	2	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	15	1

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Haematemesis	27	2
Haematochezia	49	0
Melaena	8	0
Upper gastrointestinal haemorrhage	10	0
<i>Oesophageal stenosis and obstruction</i>		
Oesophageal stenosis	3	0
<i>Oesophagitis (excl infective)</i>		
Eosinophilic oesophagitis	1	0
Oesophagitis	3	0
<i>Oral dryness and saliva altered</i>		
Aptyalism	3	0
Dry mouth	446	0
Lip dry	36	0
Saliva altered	6	0
Salivary hypersecretion	47	0
<i>Oral soft tissue disorders NEC</i>		
Angina bullosa haemorrhagica	1	0
Chapped lips	20	0
Cheilitis	23	0
Enlarged uvula	14	0
Leukoplakia oral	2	0
Lip blister	26	0
Lip disorder	4	0
Oral disorder	16	0
Oral lichen planus	11	0
Oral mucosal hypertrophy	1	0
Oral papule	1	0
Uvulitis	4	0
<i>Oral soft tissue haemorrhages</i>		
Mouth haemorrhage	15	0
Oral blood blister	12	0
Oral purpura	2	0
<i>Oral soft tissue infections</i>		
Angular cheilitis	2	0
<i>Oral soft tissue signs and symptoms</i>		
Anaesthesia oral	3	0
Burning mouth syndrome	6	0
Coating in mouth	1	0
Hypoaesthesia oral	434	0
Lip discolouration	7	0
Lip erythema	4	0
Lip exfoliation	5	0
Lip pain	50	0
Lip pruritus	14	0
Lip scab	1	0
Oral discomfort	75	0
Oral dysaesthesia	1	0
Oral mucosal blistering	13	0
Oral mucosal discolouration	1	0
Oral mucosal eruption	14	0
Oral mucosal erythema	5	0
Oral mucosal exfoliation	9	0
Oral mucosal roughening	3	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Oral mucosal scab	1	0
Oral pain	151	0
Oral pruritus	20	0
Paraesthesia oral	844	0
Pigmentation lip	1	0
Oral soft tissue swelling and oedema		
Lip oedema	4	0
Lip swelling	672	0
Mouth swelling	83	0
Oedema mouth	4	0
Palatal oedema	3	0
Palatal swelling	2	0
Pancreatic disorders NEC		
Pancreatic mass	1	0
Peptic ulcers and perforation		
Peptic ulcer	1	0
Peptic ulcer haemorrhage	11	0
Peritoneal and retroperitoneal disorders		
Ascites	1	0
Peritoneal and retroperitoneal fibrosis and adhesions		
Abdominal adhesions	2	0
Peritoneal and retroperitoneal haemorrhages		
Haemoperitoneum	1	0
Retroperitoneal haemorrhage	1	1
Rectal inflammations NEC		
Proctitis	3	0
Proctitis ulcerative	1	0
Salivary gland disorders NEC		
Salivary gland disorder	1	0
Salivary gland pain	12	0
Salivary gland enlargements		
Parotid gland enlargement	9	0
Salivary gland enlargement	5	0
Submaxillary gland enlargement	7	0
Salivary gland infections and inflammations		
Noninfective sialoadenitis	1	0
Stomatitis and ulceration		
Aphthous ulcer	47	0
Lip ulceration	16	0
Mouth ulceration	404	0
Oral mucosa erosion	1	0
Palatal ulcer	1	0
Stomatitis	58	0
Tongue disorders		
Glossitis	17	0
Hypertrophy of tongue papillae	1	0
Plicated tongue	3	0
Tongue disorder	34	0
Tongue geographic	2	0
Tongue haemorrhage	3	0
Tongue ulceration	29	0
Trichoglossia	4	0
Tongue signs and symptoms		

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Glossodynia	190	0
Scalloped tongue	5	0
Stiff tongue	4	0
Swollen tongue	440	0
Tongue blistering	17	0
Tongue coated	16	0
Tongue discolouration	33	0
Tongue discomfort	38	0
Tongue dry	13	0
Tongue eruption	9	0
Tongue erythema	10	0
Tongue exfoliation	1	0
Tongue movement disturbance	6	0
Tongue oedema	21	0
Tongue pruritus	2	0
Tongue rough	4	0
Tongue spasm	9	0
<i>Tooth missing</i>		
Tooth loss	6	0
Gastrointestinal disorders SOC TOTAL	33437	17

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site bruise	6	0
Administration site erythema	4	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	17	0
Administration site rash	5	0
Administration site reaction	1	0
Administration site swelling	4	0
Administration site urticaria	2	0
Administration site warmth	2	0
Puncture site bruise	35	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	3	0
<i>Application and instillation site reactions</i>		
Application site acne	2	0
Application site bruise	8	0
Application site burn	1	0
Application site erythema	15	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	7	0
Application site warmth	1	0
Instillation site warmth	6	0
<i>Asthenic conditions</i>		
Asthenia	1686	0
Chronic fatigue syndrome	68	0
Decreased activity	9	0
Fatigue	19947	0
Malaise	4557	0
Sluggishness	13	0
<i>Body temperature altered</i>		

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Hyperthermia	5	0
Hypothermia	22	0
Temperature regulation disorder	12	0
Breast complications associated with device		
Breast implant palpable	1	0
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	2	0
Death and sudden death		
Brain death	3	3
Cardiac death	1	1
Clinical death	1	1
Death	159	159
Decapitation	1	1
Drowning	1	0
Sudden death	26	26
Febrile disorders		
Hyperpyrexia	9	0
Pyrexia	13027	1
Feelings and sensations NEC		
Chills	8238	0
Feeling abnormal	1441	0
Feeling cold	1020	0
Feeling drunk	73	0
Feeling hot	1023	0
Feeling jittery	23	0
Feeling of body temperature change	290	0
Feeling of relaxation	3	0
Hangover	74	0
Hunger	42	0
Sensation of blood flow	3	0
Sensation of foreign body	48	0
Temperature intolerance	41	0
Thirst	303	0
Fibrosis NEC		
Fibrosis	1	0
Gait disturbances		
Gait disturbance	201	0
Gait inability	73	0
Loss of control of legs	17	0
General signs and symptoms NEC		
Adhesion	1	0
Chronic disease	1	0
Condition aggravated	192	0
Crepitations	2	0
Crying	142	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Deformity	2	0
Discharge	10	0
Disease progression	2	0
Disease recurrence	26	0
Effusion	3	0
Energy increased	20	0
Exercise tolerance decreased	23	0
Foaming at mouth	1	0
General physical health deterioration	15	2
General symptom	3	0
Glassy eyes	4	0
High-pitched crying	3	0
Illness	1646	0
Induration	15	0
Influenza like illness	2067	0
Irritability postvaccinal	2	0
Local reaction	76	0
Moaning	3	0
Multiple organ dysfunction syndrome	10	4
Nonspecific reaction	1	0
Organ failure	2	1
Perforation	2	0
Peripheral swelling	3158	0
Physical deconditioning	2	0
Pre-existing condition improved	8	0
Prolapse	1	0
Screaming	20	0
Secretion discharge	20	0
Swelling	2574	0
Swelling face	732	0
Symptom recurrence	1	0
Terminal state	1	0
Tissue irritation	1	0
Healing abnormal NEC		
Impaired healing	1	0
Implant and catheter site reactions		
Implant site discolouration	2	0
Implant site pain	2	0
Implant site rash	1	0
Implant site swelling	2	0
Implant site urticaria	1	0
Implant site warmth	3	0
Inflamations		
Granuloma	1	0
Inflammation	413	0
Papillitis	1	0
Scar inflammation	1	0
Serositis	1	0
Systemic inflammatory response syndrome	2	0
Infusion site reactions		
Infusion site coldness	1	0
Infusion site erythema	1	0
Infusion site joint effusion	1	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Infusion site joint pain	2	0
Infusion site mass	1	0
Infusion site nerve damage	1	0
Infusion site pain	1	0
Infusion site pruritus	1	0
Infusion site swelling	1	0
Infusion site urticaria	1	0
Infusion site warmth	2	0
Injection site reactions		
Injected limb mobility decreased	27	0
Injection site bruising	59	0
Injection site coldness	1	0
Injection site cyst	2	0
Injection site discolouration	5	0
Injection site discomfort	10	0
Injection site eczema	1	0
Injection site erythema	335	0
Injection site extravasation	1	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	34	0
Injection site irritation	1	0
Injection site joint discomfort	2	0
Injection site joint erythema	2	0
Injection site joint movement impairment	1	0
Injection site joint pain	13	0
Injection site lymphadenopathy	1	0
Injection site macule	1	0
Injection site mass	465	0
Injection site movement impairment	1	0
Injection site necrosis	4	0
Injection site nerve damage	1	0
Injection site oedema	15	0
Injection site pain	2638	0
Injection site paraesthesia	12	0
Injection site pruritus	170	0
Injection site rash	148	0
Injection site reaction	27	0
Injection site scab	4	0
Injection site scar	5	0
Injection site swelling	263	0
Injection site urticaria	26	0
Injection site vesicles	9	0
Injection site warmth	169	0
Interactions		
Alcohol interaction	4	0
Drug interaction	25	0
Inhibitory drug interaction	3	0
Mass conditions NEC		
Cyst	39	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Mass	60	0
Nodule	33	0
<i>Mucosal findings abnormal</i>		
Mucosa vesicle	1	0
Mucosal dryness	1	0
Mucosal haemorrhage	9	0
Mucosal inflammation	2	0
Oedema mucosal	1	0
Polyp	5	0
<i>Necrosis NEC</i>		
Fat necrosis	3	0
Necrosis	4	0
<i>Oedema NEC</i>		
Face oedema	27	0
Generalised oedema	3	0
Localised oedema	17	0
Oedema	69	0
Oedema peripheral	79	0
<i>Pain and discomfort NEC</i>		
Axillary pain	2687	0
Chest discomfort	1486	0
Chest pain	3759	0
Discomfort	423	0
Facial discomfort	19	0
Facial pain	188	0
Inflammatory pain	12	0
Non-cardiac chest pain	25	0
Pain	7721	0
Suprapubic pain	1	0
Tenderness	594	0
Visceral pain	2	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	51	0
Adverse event	2	0
Adverse food reaction	3	0
Adverse reaction	1	0
Drug ineffective	280	1
Drug intolerance	3	0
Drug resistance	1	0
Immediate post-injection reaction	2	0
Inadequate analgesia	8	0
No reaction on previous exposure to drug	36	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 changed	1	0
Therapeutic response decreased	2	0
Therapeutic response unexpected	70	0
Therapy non-responder	1	0
Treatment failure	6	0
Vaccination failure	34	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
<i>Trophic disorders</i>		
Atrophy	2	0
Calcinosis	1	0
Hyperplasia	1	0
<i>Ulcers NEC</i>		
Ulcer	30	0
Ulcer haemorrhage	1	0
<i>Vaccination site reactions</i>		
Extensive swelling of vaccinated limb	12	0
Shoulder injury related to vaccine administration	25	0
Vaccination site anaesthesia	1	0
Vaccination site bruising	111	0
Vaccination site coldness	2	0
Vaccination site cyst	5	0
Vaccination site dermatitis	1	0
Vaccination site discolouration	14	0
Vaccination site discomfort	44	0
Vaccination site dryness	1	0
Vaccination site eczema	1	0
Vaccination site erythema	560	0
Vaccination site granuloma	3	0
Vaccination site haematoma	2	0
Vaccination site haemorrhage	18	0
Vaccination site hypersensitivity	3	0
Vaccination site hypoaesthesia	16	0
Vaccination site induration	70	0
Vaccination site inflammation	51	0
Vaccination site irritation	12	0
Vaccination site joint discomfort	2	0
Vaccination site joint erythema	9	0
Vaccination site joint inflammation	1	0
Vaccination site joint movement impairment	17	0
Vaccination site joint pain	31	0
Vaccination site joint swelling	4	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	6	0
Vaccination site macule	1	0
Vaccination site mass	253	0
Vaccination site movement impairment	80	0
Vaccination site nerve damage	1	0
Vaccination site nodule	3	0
Vaccination site oedema	3	0
Vaccination site pain	1973	0
Vaccination site paraesthesia	7	0
Vaccination site phlebitis	1	0
Vaccination site pruritus	148	0
Vaccination site rash	117	0
Vaccination site reaction	31	0
Vaccination site scab	2	0
Vaccination site scar	1	0
Vaccination site swelling	515	0
Vaccination site thrombosis	1	0
Vaccination site ulcer	1	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site urticaria	10	0
Vaccination site vesicles	9	0
Vaccination site warmth	249	0
<i>Vascular complications associated with device</i>		
Vascular stent thrombosis	1	0
<i>Withdrawal and rebound effects</i>		
Drug withdrawal syndrome	4	0
Withdrawal syndrome	38	0
General disorders SOC TOTAL	90682	200

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	12	0
Cholangitis	1	0
<i>Cholecystitis and cholelithiasis</i>		
Cholecystitis	3	0
Cholecystitis acute	2	0
Cholelithiasis	10	0
<i>Cholestasis and jaundice</i>		
Cholestasis	2	0
Jaundice	21	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	12	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	6	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	26	0
Hepatomegaly	2	0
Liver tenderness	3	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	7	0
Drug-induced liver injury	2	0
Hepatic steatosis	2	0
Hepatitis	9	0
Immune-mediated hepatic disorder	1	0
Liver injury	17	0
Hepatic disorders SOC TOTAL	171	1

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	14	0
<i>Allergic conditions NEC</i>		
Allergic oedema	15	0
Allergy to animal	1	0
Allergy to arthropod bite	6	0
Allergy to arthropod sting	2	0
Allergy to metals	1	0
Allergy to sting	1	0
Hypersensitivity	863	0
Infusion related hypersensitivity reaction	3	0
Mite allergy	3	0
Multiple allergies	9	0
Serum sickness	2	0
Serum sickness-like reaction	6	0
Type I hypersensitivity	1	0
Type III immune complex mediated reaction	3	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	3	0
Allergy to vaccine	35	0
Contrast media reaction	2	0
Drug hypersensitivity	24	0
Food allergy	26	0
Milk allergy	2	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	455	2
Anaphylactic shock	50	0
Anaphylactoid reaction	20	0
Anaphylactoid shock	4	0
<i>Atopic disorders</i>		
Atopy	1	0
Seasonal allergy	104	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	41	0
<i>Immune and associated conditions NEC</i>		
Anamnestic reaction	1	0
Bacille Calmette-Guerin scar reactivation	49	0
Cytokine storm	1	0
Decreased immune responsiveness	2	0
Graft versus host disease	1	0
Haemophagocytic lymphohistiocytosis	2	0
Immune reconstitution inflammatory syndrome	1	0
Immune system disorder	20	0
Immune-mediated adverse reaction	7	0
Immunisation reaction	1	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Immune system disorders		
Immune system disorders cont'd		
Multisystem inflammatory syndrome in children	1	0
Sensitisation	4	0
Systemic immune activation	2	0
<i>Immunodeficiency disorders NEC</i>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	1	0
Immunosuppression	3	0
<i>Primary immunodeficiency syndromes</i>		
Selective IgA immunodeficiency	1	0
<i>Transplant rejections</i>		
Corneal graft rejection	6	0
Kidney transplant rejection	1	0
Solid organ transplant rejection	1	0
Transplant rejection	1	0
Immune system disorders SOC TOTAL	1833	2

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Abdominal abscess	2	0
Abdominal infection	1	0
Anal abscess	3	0
Appendicitis	36	0
Appendicitis perforated	7	0
Diverticulitis	11	0
Dysentery	1	0
Gastric infection	2	0
Gastroenteritis	26	0
Mesenteric abscess	1	0
Peritonitis	2	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	2	0
Arthritis bacterial	3	0
Bacterial colitis	1	0
Bacterial diarrhoea	1	0
Bacterial infection	13	0
Bacterial sepsis	1	0
Cellulitis	163	0
Conjunctivitis bacterial	1	0
Ear infection bacterial	1	0
Folliculitis	16	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	19	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	2	0
<i>Borrelial infections</i>		
Lyme disease	2	0
Relapsing fever	2	0
<i>Breast infections</i>		
Breast abscess	3	0
Mastitis	70	0
<i>Caliciviral infections</i>		

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Gastroenteritis norovirus	3	0
<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	59	0
Oral candidiasis	36	0
Respiratory moniliasis	1	0
Skin candida	1	0
Systemic candida	1	0
Urinary tract candidiasis	1	0
Vulvovaginal candidiasis	45	0
<i>Cardiac infections</i>		
Cardiac infection	1	0
Pericarditis infective	2	0
<i>Central nervous system and spinal infections</i>		
Brain abscess	1	0
CNS ventriculitis	1	0
Cavernous sinus thrombosis	1	0
Encephalitis	19	0
Encephalomyelitis	1	0
Meningitis	7	0
Meningitis aseptic	3	0
Myelitis	6	0
Subdural abscess	1	0
<i>Clostridia infections</i>		
Clostridium difficile infection	2	0
<i>Coronavirus infections</i>		
Asymptomatic COVID-19	15	0
COVID-19	1296	41
COVID-19 pneumonia	48	14
Coronavirus infection	7	0
Post-acute COVID-19 syndrome	2	0
Severe acute respiratory syndrome	2	0
Suspected COVID-19	63	4
<i>Coxiella infections</i>		
Q fever	10	0
<i>Cytomegaloviral infections</i>		
Cytomegalovirus infection	2	0
Cytomegalovirus syndrome	1	0
<i>Dental and oral soft tissue infections</i>		
Abscess oral	6	0
Gingivitis	10	0
Oral infection	1	0
Parotitis	10	0
Pericoronitis	2	0
Pulpitis dental	1	0
Sialoadenitis	3	0
Tongue abscess	1	0
Tooth abscess	8	0
Tooth infection	9	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
<i>Ear infections</i>		
Ear infection	77	0
Labyrinthitis	96	0
Mastoiditis	1	0
Otitis externa	2	0
Otitis media	2	0
Otitis media acute	1	0
Otitis media chronic	4	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	23	0
<i>Escherichia infections</i>		
Escherichia bacteraemia	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	65	0
Eye abscess	1	0
Eye infection	18	0
Eyelid boil	2	0
Eyelid infection	2	0
Hordeolum	25	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	15	0
Fungal skin infection	5	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
Hepatic infection	1	0
<i>Herpes viral infections</i>		
Eczema herpeticum	2	0
Genital herpes	78	0
Genital herpes simplex	6	0
Herpes ophthalmic	3	0
Herpes simplex	25	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Herpes simplex encephalitis	1	1
Herpes simplex reactivation	2	0
Herpes virus infection	10	0
Herpes zoster	1303	0
Herpes zoster disseminated	1	0
Herpes zoster meningoencephalitis	1	0
Herpes zoster oticus	13	0
Herpes zoster reactivation	1	0
Nasal herpes	4	0
Ophthalmic herpes simplex	2	0
Ophthalmic herpes zoster	3	0
Oral herpes	280	0
Varicella	25	0
Varicella zoster virus infection	2	0
Infections NEC		
Abscess	36	0
Abscess limb	7	0
Abscess soft tissue	1	0
Catheter site infection	1	0
Genital abscess	2	0
Infected bite	3	0
Infected cyst	2	0
Infection	213	0
Infection susceptibility increased	1	0
Injection site abscess	1	0
Injection site infection	5	0
Localised infection	28	0
Lymph gland infection	9	0
Lymph node abscess	5	0
Opportunistic infection	1	0
Pathogen resistance	1	0
Purulent discharge	1	0
Respiratory tract infection	10	0
Vaccination site abscess	7	0
Vaccination site infection	13	0
Vaccine breakthrough infection	23	0
Vestibulitis	2	0
Wound infection	1	0
Infectious transmissions		
Secondary transmission	8	0
Vaccine virus shedding	1	0
Influenza viral infections		
Influenza	1383	0
Klebsiella infections		
Klebsiella infection	1	0
Lower respiratory tract and lung infections		
Bronchitis	20	0
Infectious pleural effusion	1	0
Lower respiratory tract infection	194	8
Pneumonia	119	12
Pneumonia aspiration	9	6
Sputum purulent	1	0
Male reproductive tract infections		

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
Epididymitis	7	0
Orchitis	5	0
Prostate infection	2	0
<i>Molluscum contagiosum viral infections</i>		
Molluscum contagiosum	1	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
Psoas abscess	1	0
Soft tissue infection	2	0
<i>Neisseria infections</i>		
Gonorrhoea	1	0
Meningococcal bacteraemia	1	0
<i>Orthopox viral infections</i>		
Vaccinia virus infection	1	0
<i>Plasmodia infections</i>		
Malaria	2	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>		
Neutropenic sepsis	3	1
Sepsis	45	7
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	10	0
Infected skin ulcer	1	0
Injection site pustule	2	0
Nail infection	1	0
Pustule	18	0
Rash pustular	10	0
Skin infection	29	0
Subcutaneous abscess	11	0
Sweat gland infection	1	0
Vaccination site pustule	4	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Staphylococcal infections</i>		
Furuncle	38	1
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	6	0
Streptococcal abscess	1	0
Streptococcal endocarditis	1	0
Streptococcal infection	1	0
Streptococcal sepsis	1	0
<i>Tinea infections</i>		
Body tinea	3	0
Tinea infection	1	0
Tinea pedis	2	0
Tinea versicolour	3	0
<i>Treponema infections</i>		
Syphilis	2	0
<i>Trypanosomal infections</i>		
African trypanosomiasis	2	0
<i>Tuberculous infections</i>		
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	2	0
Croup infectious	1	0
Epiglottitis	1	0
Laryngitis	27	0
Nasopharyngitis	929	0
Peritonsillar abscess	3	0
Pharyngitis	30	0
Rhinitis	40	0
Sinusitis	144	0
Tonsillitis	107	0
Tracheitis	4	0
Tracheostomy infection	1	0
Upper respiratory tract infection	9	0
<i>Urinary tract infections</i>		
Cystitis	73	0
Kidney infection	43	0
Pyelonephritis	2	0
Urethritis	1	0
Urinary tract infection	181	0
<i>Vascular infections</i>		
Haematoma infection	1	0
Infected lymphocele	2	0
Infusion site infection	1	0
Lymphangitis	7	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
<i>Viral infections NEC</i>		
Arthritis viral	1	0
Conjunctivitis viral	2	0
Encephalitis viral	6	1
Eye infection viral	2	0
Gastroenteritis viral	26	0
Hepatitis viral	3	0
Meningitis viral	8	0
Meningoencephalitis viral	1	0
Oral viral infection	1	0
Pleurisy viral	1	0
Pneumonia viral	3	1
Post viral fatigue syndrome	43	0
Sweating fever	92	0
Vestibular neuronitis	28	0
Viral diarrhoea	2	0
Viral infection	49	0
Viral labyrinthitis	4	0
Viral myocarditis	2	0
Viral pericarditis	3	0
Viral pharyngitis	17	0
Viral rash	52	0
Viral sinusitis	1	0
Viral tonsillitis	1	0
Infections SOC TOTAL	8589	100

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Liver contusion	1	0
Mouth injury	3	0
Oral contusion	3	0
Palate injury	1	0
Rectal injury	1	0
Splenic rupture	7	0
Tongue injury	2	0
Tooth fracture	1	0
Tooth injury	1	0
<i>Accidental exposures to product</i>		
Accidental exposure to product	20	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	2	0
Joint injury	8	0
Meniscus injury	1	0
<i>Cardiac and vascular procedural complications</i>		
Shunt blood flow excessive	1	0
Vascular pseudoaneurysm	1	0
<i>Cardiovascular injuries</i>		
Vascular injury	6	0
<i>Cerebral injuries NEC</i>		
Brain contusion	3	0
Brain herniation	1	0
Concussion	4	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	4	0
Chemical cystitis	1	0
<i>Chest and respiratory tract injuries NEC</i>		
Bronchial injury	1	0
Chest crushing	9	0
Foreign body in throat	1	0
Traumatic lung injury	1	0
<i>Conditions caused by cold</i>		
Chillblains	53	0
Cold shock response	1	0
Frostbite	1	0
<i>Cranial nerve injuries</i>		
Vth nerve injury	1	0
<i>Ear injuries NEC</i>		
Ear injury	1	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	9	0
Exposure via breast milk	130	0
Foetal exposure during pregnancy	41	0
Maternal exposure before pregnancy	12	0
Maternal exposure during breast feeding	1548	0
Maternal exposure during pregnancy	843	0
Maternal exposure timing unspecified	10	0
Paternal exposure before pregnancy	3	0
<i>Exposures to agents or circumstances NEC</i>		
Exposure to SARS-CoV-2	3	0
Exposure to vaccinated person	4	0
<i>Eye and ear procedural complications</i>		
Toxic anterior segment syndrome	1	0
<i>Eye injuries NEC</i>		
Corneal abrasion	1	0
Eye contusion	13	0
Eye injury	18	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
<i>Foetal and neonatal conditions associated with product exposure</i>		
Intoxication by breast feeding	1	0
<i>Fractures and dislocations NEC</i>		
Bone fragmentation	1	0
Fracture	3	0
Joint dislocation	3	0
Multiple fractures	1	0
<i>Gastrointestinal and hepatobiliary procedural complications</i>		
Post procedural constipation	1	0
Postoperative ileus	1	0
Procedural nausea	8	0
Procedural vomiting	2	0
<i>Heat injuries (excl thermal burns)</i>		
Heat cramps	2	0
Heat exhaustion	3	0
Heat illness	1	0
Heat oedema	10	0
Heat stroke	3	0
<i>Intentional product use issues</i>		
Intentional dose omission	1	0
Intentional product use issue	1	0
<i>Limb fractures and dislocations</i>		
Atypical femur fracture	3	0
Clavicle fracture	24	0
Femoral neck fracture	1	0
Femur fracture	1	0
Fibula fracture	1	0
Hip fracture	2	0
Tibia fracture	1	0
Upper limb fracture	1	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
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	20	0
Prescription drug used without a prescription	2	0
Product use complaint	1	0
Product use issue	21	0
Vaccination error	5	0
Wrong dose	4	0
Wrong drug	11	0
Wrong technique in product usage process	5	0
Muscle, tendon and ligament injuries		
Epicondylitis	17	0
Ligament injury	2	0
Ligament sprain	9	0
Mallet finger	1	0
Muscle injury	23	0
Muscle rupture	8	0
Muscle strain	28	0
Post-traumatic neck syndrome	2	0
Tendon injury	6	0
Tendon rupture	16	0
Musculoskeletal procedural complications		
Periprosthetic osteolysis	1	0
Post laminectomy syndrome	1	0
Nerve injuries NEC		
Nerve injury	85	0
Neurological and psychiatric procedural complications		
Post lumbar puncture syndrome	1	0
Post procedural stroke	1	0
Procedural dizziness	11	0
Non-occupational environmental exposures		
Exposure to extreme temperature	2	0
Non-site specific injuries NEC		
Animal scratch	1	0
Arthropod bite	5	0
Arthropod sting	5	0
Bite	1	0
Electric shock	18	0
Fall	168	0
Foreign body	2	0
Injury	10	0
Multiple injuries	2	0
Nervous system injury	2	0
Post concussion syndrome	1	0
Traumatic haematoma	1	0
Wound	7	0
Wound complication	9	0
Wound haematoma	1	0
Wound haemorrhage	2	0
Wound secretion	5	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Non-site specific procedural complications</i>		
Incision site pain	3	0
Infusion related reaction	7	0
Injection related reaction	45	0
Post procedural complication	5	0
Post procedural erythema	1	0
Post procedural inflammation	1	0
Procedural pain	2	0
Seroma	1	0
<i>Occupational exposures</i>		
Occupational exposure to SARS-CoV-2	1	0
Occupational exposure to product	1	0
<i>Off label uses</i>		
Off label use	84	0
<i>Overdoses NEC</i>		
Overdose	45	0
<i>Pathways and sources of exposure</i>		
Exposure via unknown route	1	0
<i>Pelvic fractures and dislocations</i>		
Pelvic fracture	1	0
<i>Peripheral nerve injuries</i>		
Axillary nerve injury	1	0
Brachial plexus injury	1	0
Ulnar nerve injury	4	0
<i>Poisoning and toxicity</i>		
Alcohol poisoning	1	0
Poisoning	11	0
Toxicity to various agents	3	0
<i>Product administration errors and issues</i>		
Accidental overdose	7	0
Contraindicated product administered	1	0
Expired product administered	13	0
Inappropriate schedule of product administration	514	0
Incomplete course of vaccination	1	0
Incorrect dose administered	52	0
Incorrect drug administration rate	1	0
Incorrect product formulation administered	2	0
Incorrect route of product administration	4	0
Lack of vaccination site rotation	1	0
Poor quality product administered	3	0
Product administered at inappropriate site	16	0
Product administered to patient of inappropriate age	1	0
Product administration error	7	0
Product dose omission issue	5	0
Wrong product administered	20	0
<i>Product confusion errors and issues</i>		
Product label confusion	1	0
<i>Product dispensing errors and issues</i>		
Product dispensing error	3	0
<i>Product monitoring errors and issues</i>		
Drug monitoring procedure incorrectly performed	1	0
<i>Product preparation errors and issues</i>		
Product preparation error	2	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
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		
Radiation sickness syndrome	1	0
Sunburn	20	0
Renal and urinary tract injuries NEC		
Bladder injury	1	0
Foreign body in urogenital tract	1	0
Reproductive system and breast injuries		
Penis injury	1	0
Site specific injuries NEC		
Back injury	1	0
Face crushing	2	0
Face injury	1	0
Head injury	33	0
Limb crushing injury	3	0
Limb injury	101	0
Nasal injury	1	0
Neck crushing	1	0
Neck injury	1	0
Site specific procedural complications NEC		
Axillary web syndrome	1	0
Skin injuries NEC		
Contusion	1097	0
Nail avulsion	1	0
Scar	21	0
Scratch	7	0
Skin abrasion	6	0
Skin injury	4	0
Skin laceration	2	0
Skin wound	3	0
Splinter	1	0
Subcutaneous haematoma	2	0
Skin procedural complications		
Dermal filler overcorrection	1	0
Recall phenomenon	1	0
Skull fractures, facial bone fractures and dislocations		
Facial bones fracture	1	0
Fractured skull depressed	1	0
Spinal cord injuries NEC		
Spinal cord injury cervical	1	0
Spinal fractures and dislocations		
Spinal fracture	4	0
Stoma complications		
Gastrointestinal stoma complication	2	0
Stoma site discharge	1	0
Stoma site extravasation	1	0
Stoma site haemorrhage	1	0
Thermal burns		

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Airway burns	1	0
Burn oesophageal	2	0
Burn of internal organs	2	0
Burn oral cavity	4	0
Burns second degree	6	0
Burns third degree	3	0
Thermal burn	20	0
Thermal burns of eye	12	0
<i>Underdoses NEC</i>		
Underdose	6	0
<i>Vaccination related complications</i>		
Vaccination complication	46	0
Injuries SOC TOTAL	5720	1

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Investigations		
<i>Adrenal cortex tests</i>		
Cortisol decreased	4	0
<i>Adrenal medulla tests</i>		
Epinephrine abnormal	1	0
Epinephrine increased	1	0
<i>Auditory and vestibular diagnostic procedures</i>		
Acoustic stimulation tests	5	0
Audiogram abnormal	1	0
<i>Autoimmunity analyses</i>		
Antinuclear antibody	1	0
Antinuclear antibody increased	1	0
Antinuclear antibody positive	2	0
Rheumatoid factor	3	0
<i>Bacteria identification and serology (excl mycobacteria)</i>		
Bacterial test positive	1	0
Klebsiella test positive	1	0
<i>Blood counts NEC</i>		
Full blood count	5	0
Full blood count abnormal	2	0
<i>Blood gas and acid base analyses</i>		
Acid base balance abnormal	1	0
Blood lactic acid	4	0
Blood lactic acid decreased	1	0
Blood lactic acid increased	5	0
Blood pH	8	0
Blood pH increased	8	0
Oxygen consumption	1	0
Oxygen consumption decreased	2	0
Oxygen saturation	9	0
Oxygen saturation decreased	64	0
PO2 decreased	1	0
<i>Bone marrow and immune tissue histopathology procedures</i>		
Aspiration bone marrow	1	0
Biopsy lymph gland	1	0
<i>Bone marrow and immune tissue imaging procedures</i>		
Lymph nodes scan abnormal	1	0
Scan lymph nodes	4	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose	8	0
Blood glucose abnormal	11	0
Blood glucose decreased	30	0
Blood glucose fluctuation	15	0
Blood glucose increased	93	0
Blood glucose normal	1	0
Glycosylated haemoglobin increased	1	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	35	0
Heart sounds	5	0
Heart sounds abnormal	4	0
<i>Cardiac function diagnostic procedures</i>		
Cardiac monitoring	1	0
Cardiac output	1	0
Central venous pressure	1	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Echocardiogram	1	0
Ejection fraction decreased	1	0
Myocardial strain imaging	1	0
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	1	0
Histamine level increased	1	0
Inflammatory marker decreased	1	0
Inflammatory marker increased	3	0
Renin	1	0
Cholesterol analyses		
Blood cholesterol increased	7	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	2	0
Bleeding time abnormal	1	0
Bleeding time prolonged	7	0
Blood thromboplastin	1	0
Clot retraction	2	1
Coagulation factor VIII level decreased	1	0
Coagulation time prolonged	9	0
Coagulation time shortened	4	0
Fibrin D dimer increased	13	0
International normalised ratio abnormal	7	0
International normalised ratio decreased	21	0
International normalised ratio fluctuation	2	0
International normalised ratio increased	49	0
Platelet factor 4	1	0
Prothrombin time shortened	1	0
Digestive enzymes		
Amylase increased	1	0
ECG investigations		
Electrocardiogram	5	0
Electrocardiogram QRS complex prolonged	1	0
Electrocardiogram QT prolonged	8	0
Electrocardiogram ST segment depression	2	0
Electrocardiogram ST segment elevation	11	0
Electrocardiogram ST-T segment abnormal	2	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Electrocardiogram T wave inversion	4	0
Electrocardiogram abnormal	18	0
Electrocardiogram change	1	0
Electrocardiogram normal	2	0
Electrocardiogram repolarisation abnormality	1	0
QRS axis abnormal	1	0
Endocrine analyses and imaging NEC		
Hormone level abnormal	49	0
Faecal analyses NEC		
Faecal calprotectin	2	0
Faecal calprotectin increased	4	0
Fertility analyses		
Infertility tests	1	0
Semen analysis abnormal	1	0
Sperm concentration	2	0
Sperm concentration decreased	1	0
Foetal and neonatal diagnostic procedures		
Foetal heart rate abnormal	3	2
Foetal heart rate increased	1	0
Foetal monitoring	1	0
Foetal non-stress test	1	0
Gastrointestinal and abdominal imaging procedures		
Colonoscopy	1	0
Computerised tomogram abdomen	1	0
Laparoscopy	1	0
Sigmoidoscopy abnormal	1	0
X-ray gastrointestinal tract abnormal	1	0
X-ray with contrast upper gastrointestinal tract	1	0
Gastrointestinal function diagnostic procedures		
Gastric pH decreased	1	0
Gastrointestinal, pancreatic and APUD hormone analyses		
Blood insulin	1	0
Blood insulin decreased	1	0
Haematological analyses NEC		
Blood viscosity abnormal	1	0
Plasma viscosity	1	0
Plasma viscosity abnormal	1	0
Red blood cell sedimentation rate increased	6	0
Heart rate and pulse investigations		
Carotid pulse	1	0
Heart rate	406	0
Heart rate abnormal	55	0
Heart rate decreased	71	0
Heart rate increased	793	0
Heart rate irregular	180	0
Heart rate normal	1	0
Maximum heart rate	2	0
Pulse abnormal	17	0
Pulse pressure increased	1	0
Radial pulse abnormal	1	0
Sinus rhythm	7	0
Imaging procedures NEC		
Computerised tomogram	3	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Magnetic resonance imaging	4	0
Magnetic resonance imaging abnormal	1	0
Scan	2	0
X-ray	1	0
Immune response protein analyses NEC		
Cytokine test	1	0
Immunoglobulin analyses		
Blood immunoglobulin G increased	1	0
Blood immunoglobulin M	1	0
Blood immunoglobulin M increased	1	0
Immunoglobulins	1	0
Immunology analyses NEC		
Antibody test	4	0
Immunology test	10	0
Immunology skin tests NEC		
Allergy alert test	1	0
Skin test positive	1	0
Investigations NEC		
Blood test	22	0
Blood test abnormal	45	0
False positive investigation result	1	0
Laboratory test	1	0
Polymerase chain reaction	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	23	0
Aspartate aminotransferase	1	0
Aspartate aminotransferase abnormal	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	27	0
Liver function test increased	24	0
Transaminases increased	5	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
Culture urine	1	0
Mineral and electrolyte analyses		
Blood copper increased	1	0
Blood iron	2	0
Blood iron decreased	9	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
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	3	0
Blood sodium decreased	10	0
Serum ferritin	1	0
Serum ferritin decreased	4	0
Serum ferritin increased	1	0
Sweat test	1	0
Urine copper	1	0
<i>Musculoskeletal and soft tissue imaging procedures</i>		
Skull X-ray	6	0
<i>Musculoskeletal and soft tissue tests NEC</i>		
Swollen joint count increased	1	0
<i>Mycobacteria identification and serology</i>		
Tuberculin test positive	1	0
<i>Neurologic diagnostic procedures</i>		
Coma scale abnormal	4	0
Hoover's sign of leg paresis	1	0
Joint position sense decreased	1	0
Lumbar puncture	7	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	233	0
Body temperature abnormal	40	0
Body temperature decreased	38	0
Body temperature fluctuation	45	0
Body temperature increased	380	0
Body temperature normal	1	0
Breath sounds	1	0
Breath sounds abnormal	2	0
General physical condition abnormal	1	0
Grip strength	2	0
Grip strength decreased	22	0
Head lag	7	0
Lymph node palpable	38	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	2	0
Respiratory rate	9	0
Respiratory rate decreased	20	0
Respiratory rate increased	35	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Skin temperature	38	0
Temperature difference of extremities	9	0
Weight	1	0
Weight decreased	95	0
Weight increased	34	0
<i>Pituitary analyses anterior</i>		
Blood corticotrophin	1	0
Blood follicle stimulating hormone increased	1	0
Blood growth hormone	3	0
Blood prolactin	2	0
Blood prolactin increased	2	0
Blood thyroid stimulating hormone decreased	2	0
Blood thyroid stimulating hormone increased	5	0
<i>Platelet analyses</i>		
Mean platelet volume decreased	1	0
Mean platelet volume increased	1	0
Platelet count	3	0
Platelet count decreased	70	0
Platelet count increased	4	0
<i>Protein analyses NEC</i>		
Alpha 1 globulin decreased	1	0
Alpha 2 globulin decreased	1	0
C-reactive protein increased	18	0
<i>Red blood cell analyses</i>		
Haematocrit	1	0
Haematocrit decreased	1	0
Haematocrit increased	1	0
Haemoglobin	2	0
Haemoglobin decreased	11	0
Haemoglobin increased	1	0
Red blood cell count decreased	2	0
Red blood cell rouleaux formation present	1	0
<i>Renal function analyses</i>		
Blood creatinine increased	2	0
Glomerular filtration rate decreased	3	0
<i>Reproductive hormone analyses</i>		
Blood oestrogen decreased	2	0
Blood testosterone decreased	1	0
Blood testosterone increased	1	0
False negative pregnancy test	7	0
Female sex hormone level	3	0
Human chorionic gonadotropin increased	1	0
Pregnancy test	18	0
Pregnancy test false positive	1	0
Pregnancy test positive	1	0
<i>Reproductive organ and breast histopathology procedures</i>		
Biopsy endometrium	1	0
Smear cervix	2	0
<i>Reproductive organ and breast imaging procedures</i>		
Breast scan	1	0
Hysteroscopy	2	0
<i>Respiratory and pulmonary function diagnostic procedures</i>		
Forced expiratory volume increased	2	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Fractional exhaled nitric oxide normal	1	0
Maximal voluntary ventilation	1	0
Peak expiratory flow rate	1	0
Peak expiratory flow rate decreased	4	0
Pulmonary function test	3	0
Total lung capacity decreased	3	0
Vital capacity	1	0
<i>Respiratory tract and thoracic histopathology procedures</i>		
Sputum abnormal	3	0
<i>Respiratory tract and thoracic imaging procedures</i>		
Chest X-ray	18	0
Chest X-ray abnormal	1	0
Chest X-ray normal	2	0
Chest scan	2	0
Computerised tomogram thorax	1	0
<i>Skeletal and cardiac muscle analyses</i>		
Blood creatine phosphokinase increased	5	0
Muscle enzyme	1	0
Myocardial necrosis marker	1	0
Myocardial necrosis marker increased	2	0
Troponin I increased	1	0
Troponin T increased	1	0
Troponin increased	13	0
<i>Therapeutic drug monitoring analyses</i>		
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
<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	6	0
<i>Tissue enzyme analyses NEC</i>		
Blood alkaline phosphatase increased	4	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	14	0
Blood urine present	46	0
Cells in urine	1	0
Glucose urine present	1	0
Protein urine absent	1	0
Urine analysis abnormal	6	0
Urine uric acid increased	1	0
pH urine	5	0
pH urine increased	2	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>Urinary tract function analyses NEC</i>		
Urine output	13	0
Urine output decreased	12	0
Urine output increased	6	0
<i>Urinary tract histopathology procedures</i>		
Urine cytology	1	0
<i>Urinary tract imaging procedures</i>		
Cystoscopy	2	0
Ultrasound kidney normal	1	0
<i>Vascular imaging procedures NEC</i>		
Venogram	2	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure abnormal	7	0
Blood pressure decreased	70	0
Blood pressure diastolic	2	0
Blood pressure diastolic decreased	1	0
Blood pressure diastolic increased	2	0
Blood pressure increased	206	0
Blood pressure measurement	34	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	4	0
Epstein-Barr virus test positive	1	0
HIV test	1	0
SARS-CoV-1 test	1	0
SARS-CoV-1 test positive	1	0
SARS-CoV-2 antibody test	12	0
SARS-CoV-2 antibody test negative	16	0
SARS-CoV-2 antibody test positive	4	0
SARS-CoV-2 test	34	0
SARS-CoV-2 test false negative	3	0
SARS-CoV-2 test false positive	4	0
SARS-CoV-2 test negative	8	0
SARS-CoV-2 test positive	97	0
Viral test	4	0
Viral test positive	1	0
<i>Vitamin analyses</i>		
Blood folate decreased	6	0
Vitamin B12	1	0
Vitamin B12 abnormal	2	0
Vitamin B12 decreased	2	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 decreased	1	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Eosinophil count increased	3	0
Lymphocyte count	2	0
Lymphocyte count decreased	3	0
Lymphocyte count increased	1	0
Monocyte count increased	1	0
Neutrophil count	2	0
Neutrophil count decreased	9	0
Neutrophil count increased	3	0
White blood cell count	3	0
White blood cell count decreased	11	0
White blood cell count increased	11	0
Investigations SOC TOTAL	4585	3

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	16	0
Decreased appetite	1065	0
Diet refusal	1	0
Eating disorder symptom	2	0
Food craving	12	0
Food refusal	14	0
Hyperphagia	14	0
Hypophagia	17	0
Increased appetite	30	0
Salt craving	2	0
<i>Calcium metabolism disorders</i>		
Hypocalcaemia	3	0
Tetany	3	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	44	0
Diabetes mellitus inadequate control	14	1
Increased insulin requirement	2	0
Insulin resistant diabetes	1	0
Latent autoimmune diabetes in adults	2	0
Type 1 diabetes mellitus	15	0
Type 2 diabetes mellitus	4	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	86	0
<i>Electrolyte imbalance NEC</i>		
Electrolyte imbalance	1	0
Fluid imbalance	2	0
<i>Fat soluble vitamin deficiencies and disorders</i>		
Vitamin D deficiency	4	0
<i>Fluid intake increased</i>		
Polydipsia	6	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Alcohol intolerance	3	0
Breast milk substitute intolerance	1	0
Dairy intolerance	3	0
Food intolerance	16	0
Gluten sensitivity	7	0
Histamine intolerance	4	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	16	0
Abnormal weight gain	19	0
Cachexia	1	0
Feeding disorder	68	0
Food aversion	8	0
Malnutrition	1	0
Neonatal insufficient breast milk syndrome	3	0
Obesity	1	0
Overweight	1	0
Poor feeding infant	15	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Weight loss poor	3	0
Hyperglycaemic conditions NEC		
Glucose tolerance impaired	1	0
Hyperglycaemia	64	0
Insulin resistance	4	0
Hypoglycaemic conditions NEC		
Glycopenia	1	0
Hypoglycaemia	75	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	5	1
Lactic acidosis	2	0
Metabolic acidosis	2	0
Metabolic disorders NEC		
Metabolic disorder	1	0
Mixed acid-base disorders		
Acidosis	4	0
Potassium imbalance		
Hyperkalaemia	5	0
Hypokalaemia	3	0
Hypokalaemic syndrome	1	0
Sodium imbalance		
Hyponatraemia	8	0
Hyponatraemic syndrome	3	0
Salt intoxication	1	0
Sugar intolerance (excl glucose intolerance)		
Lactose intolerance	2	0
Total fluid volume decreased		
Dehydration	186	0
Total fluid volume increased		
Fluid retention	49	0
Hypervolaemia	5	0
Vitamin deficiencies NEC		
Hypovitaminosis	5	0
Water soluble vitamin deficiencies		
Folate deficiency	4	0
Vitamin B12 deficiency	5	0
Metabolic disorders SOC TOTAL	1996	2

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	264	0
Arthropathy	25	0
Autoimmune arthritis	7	0
Haemarthrosis	5	0
Joint microhaemorrhage	1	0
Palindromic rheumatism	1	0
Polyarthritis	15	0
Rheumatic fever	2	0
Sacroiliitis	5	0
Seronegative arthritis	2	0
<i>Bone disorders NEC</i>		
Bone cyst	1	0
Exostosis	1	0
Jaw disorder	4	0
Medial tibial stress syndrome	4	0
Osteitis	6	0
Osteonecrosis	1	0
Osteonecrosis of jaw	3	0
Spinal disorder	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	328	0
Bone swelling	7	0
Coccydynia	3	0
Metatarsalgia	1	0
Pain in jaw	339	0
Pubic pain	2	0
Spinal pain	66	0
<i>Bursal disorders</i>		
Bursitis	63	0
<i>Cartilage disorders</i>		
Chondritis	1	0
Costochondritis	79	0
Osteochondritis	1	0
Polychondritis	3	0
<i>Connective tissue disorders NEC</i>		
Connective tissue disorder	1	0
Polymyalgia rheumatica	54	0
Reynold's syndrome	1	0
Sjogren's syndrome	5	0
Systemic scleroderma	1	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	2	0
Foot deformity	1	0
Hand deformity	2	0
Knee deformity	1	0
Limb deformity	4	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Musculoskeletal deformity	1	0
Fractures NEC		
Osteoporotic fracture	1	0
Intervertebral disc disorders NEC		
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 instability	1	0
Joint laxity	3	0
Joint lock	23	0
Patellofemoral pain syndrome	1	0
Periarthritis	155	0
Rotator cuff syndrome	28	0
Temporomandibular joint syndrome	8	0
Joint related signs and symptoms		
Arthralgia	7984	0
Jaw clicking	6	0
Joint effusion	15	0
Joint noise	33	0
Joint range of motion decreased	30	0
Joint stiffness	216	0
Joint swelling	482	0
Joint vibration	3	0
Joint warmth	14	0
Loose body in joint	1	0
Ligament disorders		
Ligament pain	2	0
Symphysiolysis	1	0
Lupus erythematosus (incl subtypes)		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	21	0
Metabolic bone disorders		
Osteopenia	3	0
Osteoporosis	3	0
Muscle infections and inflammations		
Antisynthetase syndrome	3	0
Immune-mediated myositis	1	0
Myositis	33	0
Polymyositis	8	0
Muscle pains		
Fibromyalgia	100	0
Myalgia	9677	1
Myalgia intercostal	1	0
Myofascial pain syndrome	11	0
Muscle related signs and symptoms NEC		
Haematoma muscle	1	0
Muscle atrophy	20	0
Muscle discomfort	7	0
Muscle disorder	6	0
Muscle fatigue	315	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Muscle haemorrhage	1	0
Muscle mass	4	0
Muscle oedema	1	0
Muscle spasms	1896	0
Muscle swelling	30	0
Muscle tightness	79	0
Muscle twitching	442	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	15	0
Nuchal rigidity	10	0
Torticollis	6	0
Trismus	30	0
<i>Muscle weakness conditions</i>		
Muscular weakness	838	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Back disorder	2	0
Chest wall mass	1	0
Growth disorder	2	0
Limb mass	20	0
Mandibular mass	2	0
Mastication disorder	4	0
Mobility decreased	101	0
Musculoskeletal disorder	11	0
Musculoskeletal stiffness	1130	0
Posture abnormal	1	0
Sacroiliac joint dysfunction	1	0
Weight bearing difficulty	3	0
<i>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</i>		
Head deformity	2	0
<i>Musculoskeletal and connective tissue infections and inflammations NEC</i>		
Dactylitis	2	0
Dupuytren's contracture	1	0
Fasciitis	1	0
Plantar fasciitis	8	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	2152	0
Flank pain	61	0
Limb discomfort	1365	0
Musculoskeletal chest pain	210	0
Musculoskeletal discomfort	87	0
Musculoskeletal pain	107	0
Neck pain	1699	0
Pain in extremity	11439	1
Rheumatic disorder	14	0
Sacral pain	3	0
<i>Myopathies</i>		
Myopathy	6	0
Rhabdomyolysis	11	0
<i>Osteoarthropathies</i>		
Nodal osteoarthritis	1	0
Osteoarthritis	41	0
Spinal osteoarthritis	1	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
<i>Psoriatic arthropathies</i>		
Psoriatic arthropathy	16	0
<i>Rheumatoid arthropathies</i>		
Juvenile idiopathic arthritis	1	0
Rheumatoid arthritis	108	0
Still's disease	2	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	225	0
Fluctuance	1	0
Groin pain	98	0
Neck mass	32	0
Purple glove syndrome	1	0
Soft tissue disorder	3	0
Soft tissue swelling	6	0
<i>Spine and neck deformities</i>		
Kyphosis	2	0
Lordosis	1	0
Neck deformity	1	0
Scoliosis	1	0
Spinal stenosis	1	0
<i>Spondyloarthropathies</i>		
Ankylosing spondylitis	6	0
Arthritis reactive	41	0
Spondylitis	2	0
Spondyloarthropathy	1	0
<i>Synovial disorders</i>		
Synovial cyst	18	0
Synovitis	10	0
<i>Tendon disorders</i>		
Enthesopathy	2	0
Posterior tibial tendon dysfunction	1	0
Tendon disorder	5	0
Tendon pain	20	0
Tendonitis	37	0
Tenosynovitis	3	0
Tenosynovitis stenosaurs	2	0
Trigger finger	28	0
<i>Trunk deformities</i>		
Drooping shoulder syndrome	1	0
Shoulder deformity	2	0
Muscle & tissue disorders SOC TOTAL	43063	2

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Neoplasms		
<i>B-cell lymphomas NEC</i>		
B-cell lymphoma	2	1
Follicular lymphoma	3	0
<i>Bone neoplasms malignant (excl sarcomas)</i>		
Bone cancer	1	1
<i>Bone neoplasms unspecified malignancy</i>		
Bone neoplasm	1	0
<i>Breast and nipple neoplasms benign</i>		
Benign breast neoplasm	1	0
Fibroadenoma of breast	1	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	35	0
Breast cancer female	1	0
Breast cancer male	1	0
Breast cancer stage I	1	0
Breast cancer stage III	3	0
Invasive ductal breast carcinoma	1	0
Triple negative breast cancer	2	0
<i>Cardiovascular neoplasms benign</i>		
Haemangioma	1	0
Pericardial lipoma	1	0
<i>Cervix neoplasms malignant</i>		
Cervix carcinoma	1	0
<i>Colorectal neoplasms malignant</i>		
Colon cancer	1	0
Colorectal cancer	1	0
Rectal cancer	2	0
<i>Endocrine neoplasms malignant and unspecified NEC</i>		
Neuroendocrine tumour	1	0
Thyroid neoplasm	1	0
<i>Endometrial neoplasms malignant</i>		
Endometrial cancer	1	0
<i>Follicular lymphomas</i>		
Primary gastrointestinal follicular lymphoma	1	0
<i>Gastric neoplasms malignant</i>		
Gastric cancer	1	1
<i>Gastrointestinal neoplasms malignant NEC</i>		
Gastrointestinal carcinoma	3	0
<i>Hepatobiliary neoplasms malignancy unspecified</i>		
Hepatic neoplasm	1	0
<i>Hodgkin's disease NEC</i>		
Hodgkin's disease	5	0
<i>Islet cell neoplasms and APUDoma NEC</i>		
Pancreatic neuroendocrine tumour	1	0
<i>Leukaemias NEC</i>		
Leukaemia	4	1
<i>Leukaemias acute NEC</i>		
Acute leukaemia	2	0
<i>Leukaemias chronic NEC</i>		
Chronic leukaemia	1	0
<i>Leukaemias chronic lymphocytic</i>		
Chronic lymphocytic leukaemia	3	0
<i>Leukaemias chronic myeloid</i>		

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Chronic myeloid leukaemia	1	0
Lip and oral cavity neoplasms malignant		
Lip and/or oral cavity cancer recurrent	1	0
Lymphomas unspecified NEC		
Lymphoma	29	1
Metastases to specified sites		
Metastases to bone	1	0
Metastases to liver	1	0
Metastases to lymph nodes	5	0
Metastases to unknown and unspecified sites		
Metastasis	1	0
Mycoses fungoides		
Cutaneous T-cell lymphoma	1	0
Myelodysplastic syndromes		
Myelodysplastic syndrome	3	0
Myeloproliferative disorders (excl leukaemias)		
Essential thrombocythaemia	1	0
Neoplasms malignant site unspecified NEC		
Adenocarcinoma metastatic	1	0
Metastatic neoplasm	2	0
Neoplasm malignant	7	0
Second primary malignancy	1	0
Squamous cell carcinoma	5	0
Neoplasms unspecified malignancy and site unspecified NEC		
Neoplasm	1	0
Neoplasm recurrence	1	0
Nervous system neoplasms benign NEC		
Cranial nerve neoplasm benign	1	0
Neurilemmoma benign	1	0
Nervous system neoplasms unspecified malignancy NEC		
Brain neoplasm	2	0
Spinal cord neoplasm	1	0
Neuromas		
Acoustic neuroma	2	0
Non-Hodgkin's lymphomas NEC		
Non-Hodgkin's lymphoma	2	0
Ocular neoplasms benign		
Eye naevus	1	0
Oesophageal neoplasms malignant		
Oesophageal cancer metastatic	4	0
Oncologic complications and emergencies		
Cancer pain	1	0
Tumour haemorrhage	1	0
Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified		
Tonsil cancer	3	0
Ovarian neoplasms malignant (excl germ cell)		
Ovarian cancer	1	0
Pancreatic neoplasms malignant (excl islet cell and carcinoid)		
Pancreatic carcinoma	4	0
Plasma cell myelomas		
POEMS syndrome	1	0
Plasma cell myeloma	1	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
<i>Plasma cell neoplasms NEC</i>		
TEMPI syndrome	1	0
<i>Prostatic neoplasms malignant</i>		
Prostate cancer	4	0
<i>Renal neoplasms malignant</i>		
Renal cancer	2	0
<i>Reproductive neoplasms female benign NEC</i>		
Benign hydatidiform mole	1	0
<i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i>		
Bronchial carcinoma	1	0
Lung neoplasm malignant	10	0
<i>Skin melanomas (excl ocular)</i>		
Malignant melanoma	1	0
<i>Skin neoplasms benign</i>		
Acrochordon	4	0
Anogenital warts	7	0
Haemangioma of skin	4	0
Melanocytic naevus	6	0
Pyogenic granuloma	1	0
Skin papilloma	17	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	7	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	10	0
Neoplasms SOC TOTAL	260	5

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	7	0
Extensor plantar response	2	0
Hoffmann's sign	1	0
Hyperreflexia	4	0
Hyporeflexia	7	0
Reflexes abnormal	2	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	25	0
<i>Absence seizures</i>		
Petit mal epilepsy	25	0
<i>Acute polyneuropathies</i>		
Acute motor axonal neuropathy	1	0
Guillain-Barre syndrome	65	1
Miller Fisher syndrome	1	0
Subacute inflammatory demyelinating polyneuropathy	1	0
<i>Autonomic nervous system disorders</i>		
Anticholinergic syndrome	1	0
Autonomic nervous system imbalance	9	0
Autonomic neuropathy	2	0
Horner's syndrome	1	0
Orthostatic intolerance	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 haemorrhage	1	1
Brain stem infarction	1	1
Brain stem stroke	1	0
Carotid artery occlusion	1	0
Carotid artery thrombosis	3	0
Cerebellar haemorrhage	2	0
Cerebellar infarction	3	0
Cerebellar ischaemia	1	0
Cerebellar stroke	8	1
Cerebral artery embolism	3	1
Cerebral artery occlusion	2	0
Cerebral artery thrombosis	3	0
Cerebral haemorrhage	45	8
Cerebral infarction	26	2
Cerebral thrombosis	13	0
Cerebrovascular accident	365	16
Embolic stroke	6	0
Haemorrhage intracranial	9	2
Haemorrhagic cerebral infarction	1	0
Haemorrhagic stroke	10	3
Internal capsule infarction	1	0
Intracranial haematoma	1	0
Ischaemic cerebral infarction	1	0
Ischaemic stroke	46	2
Lacunar infarction	2	0
Lacunar stroke	3	0
Lateral medullary syndrome	1	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Pseudostroke	1	0
Subarachnoid haemorrhage	14	6
Thalamic infarction	1	0
Thrombotic stroke	3	1
Central nervous system inflammatory disorders NEC		
Arachnoiditis	1	0
Gliosis	1	0
Central nervous system vascular disorders NEC		
Brain hypoxia	2	1
Carotid arteriosclerosis	1	0
Central nervous system vasculitis	1	0
Cerebral amyloid angiopathy	1	0
Cerebral congestion	3	0
Cerebral small vessel ischaemic disease	1	0
Cerebrovascular disorder	2	0
Post cardiac arrest syndrome	1	0
Reversible cerebral vasoconstriction syndrome	1	0
Cerebrovascular venous and sinus thrombosis		
Cerebral venous sinus thrombosis	49	5
Cerebral venous thrombosis	6	0
Superior sagittal sinus thrombosis	6	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	13	0
Diabetic coma	1	0
Hypoglycaemic coma	1	0
Coordination and balance disturbances		
Ataxia	13	0
Balance disorder	359	0
Cerebellar ataxia	1	0
Coordination abnormal	51	0
Dysdiadochokinesis	1	0
Dysstasia	53	0
Nystagmus	11	0
Cortical dysfunction NEC		
Alexia	2	0
Aphasia	78	0
Apraxia	1	0
Dysgraphia	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

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Cranial nerve paralysis	1	0
Dementia (excl Alzheimer's type)		
Dementia	17	0
Dementia with Lewy bodies	1	0
Senile dementia	1	0
Demyelinating disorders NEC		
Acute disseminated encephalomyelitis	6	0
Clinically isolated syndrome	1	0
Demyelination	8	0
Neuromyelitis optica spectrum disorder	2	0
Disturbances in consciousness NEC		
Altered state of consciousness	11	0
Consciousness fluctuating	2	0
Depressed level of consciousness	42	0
Infant sedation	1	0
Lethargy	2052	0
Loss of consciousness	591	0
Postictal state	5	0
Sedation	8	0
Somnolence	928	0
Stupor	4	0
Syncope	1995	0
Disturbances in sleep phase rhythm		
Circadian rhythm sleep disorder	1	0
Irregular sleep phase	2	0
Irregular sleep wake rhythm disorder	1	0
Dyskinesias and movement disorders NEC		
Akathisia	5	0
Bradykinesia	18	0
Clumsiness	20	0
Dyskinesia	60	0
Extrapyramidal disorder	2	0
Fine motor skill dysfunction	11	0
Foetal movement disorder	4	0
Hyperkinesia	3	0
Hypokinesia	66	0
Motor dysfunction	3	0
Movement disorder	50	0
Psychomotor hyperactivity	23	0
Synkinesis	2	0
Tardive dyskinesia	2	0
Dystonias		
Dystonia	15	0
Writer's cramp	1	0
Encephalitis NEC		
Encephalitis autoimmune	1	0
Limbic encephalitis	1	0
Noninfective encephalitis	5	0
Encephalopathies NEC		
Autoimmune encephalopathy	1	1
Encephalopathy	4	0
Hashimoto's encephalopathy	1	0
Posterior reversible encephalopathy syndrome	1	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Eye movement disorders</i>		
IIIrd nerve disorder	1	0
IIIrd nerve paralysis	7	0
IVth nerve paralysis	1	0
Microvascular cranial nerve palsy	1	0
VIth nerve disorder	1	0
VIth nerve paralysis	10	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	465	0
Facial nerve disorder	8	0
Facial paralysis	357	0
Facial paresis	87	0
Facial spasm	47	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	49	0
<i>Headaches NEC</i>		
Cervicogenic headache	3	0
Cluster headache	209	0
Cold-stimulus headache	23	0
Drug withdrawal headache	2	0
Exertional headache	8	0
External compression headache	2	0
Headache	23964	0
Medication overuse headache	2	0
New daily persistent headache	4	0
Occipital neuralgia	11	0
Ophthalmoplegic migraine	1	0
Primary cough headache	4	0
Primary headache associated with sexual activity	7	0
Sinus headache	324	0
Tension headache	515	0
Thunderclap headache	11	0
Vascular headache	14	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	7	2
Idiopathic intracranial hypertension	7	0
Intracranial pressure increased	1	0
<i>Intellectual disabilities</i>		
Intellectual disability	3	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Sciatica	87	0
<i>Memory loss (excl dementia)</i>		
Amnesia	171	0
Memory impairment	176	0
Transient global amnesia	9	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	81	0
Cognitive linguistic deficit	1	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Disturbance in attention	296	0
Mental impairment	45	0
Migraine headaches		
Hemiplegic migraine	29	0
Migraine	2752	0
Migraine with aura	177	0
Migraine without aura	17	0
Ophthalmic migraine	5	0
Retinal migraine	32	0
Typical aura without headache	7	0
Vestibular migraine	18	0
Mixed cranial nerve disorders		
Bulbar palsy	2	0
Mononeuropathies		
Carpal tunnel syndrome	22	0
Cubital tunnel syndrome	3	0
Meralgia paraesthetica	1	0
Mononeuritis	2	0
Mononeuropathy	4	0
Nerve compression	24	0
Peripheral nerve lesion	1	0
Peroneal nerve palsy	14	0
Sciatic nerve neuropathy	2	0
Ulnar nerve palsy	2	0
Ulnar neuritis	1	0
Ulnar tunnel syndrome	2	0
Motor neurone diseases		
Lower motor neurone lesion	1	0
Motor neurone disease	1	0
Multiple sclerosis acute and progressive		
Band sensation	1	0
Multiple sclerosis	28	0
Multiple sclerosis relapse	22	0
Tumefactive multiple sclerosis	1	1
Muscle tone abnormal		
Drop attacks	1	0
Hypertonia	2	0
Hypotonia	28	0
Morvan syndrome	1	0
Muscle tone disorder	1	0
Serotonin syndrome	1	0
Stiff leg syndrome	1	0
Myelitis (incl infective)		
Myelitis transverse	25	0
Narcolepsy and hypersomnia		
Cataplexy	3	0
Hypersomnia	102	0
Narcolepsy	7	0
Nervous system disorders NEC		
Central nervous system lesion	2	0
Cerebral disorder	1	0
Nervous system disorder	14	0
Neurotoxicity	4	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Psychomotor skills impaired	1	0
Neurologic visual problems NEC		
Hemianopia	1	0
Hemianopia homonymous	2	0
Quadrantanopia	1	0
Tunnel vision	18	0
Neurological signs and symptoms NEC		
Agitation neonatal	1	0
Clonus	4	0
Decerebrate posture	1	0
Decorticate posture	1	0
Dizziness	9079	0
Dizziness exertional	40	0
Dizziness postural	681	0
Drooling	22	0
Fontanelle bulging	2	0
Head discomfort	315	0
Hyporesponsive to stimuli	2	0
Inability to crawl	2	0
Infant irritability	10	0
Myoclonus	28	0
Neurological symptom	42	0
Patient elopement	1	0
Persistent postural-perceptual dizziness	15	0
Presyncope	586	0
Sensory overload	4	0
Slow response to stimuli	4	0
Tongue biting	7	0
Unresponsive to stimuli	43	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	23	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	247	0
Hyposmia	16	0
Parosmia	235	0
Optic nerve disorders NEC		
Optic neuritis	26	0
Paraesthesias and dysaesthesias		
Burning feet syndrome	7	0
Burning sensation	493	0
Burning sensation mucosal	2	0
Dysaesthesia	7	0
Formication	39	0
Hand-arm vibration syndrome	3	0
Hemianaesthesia	1	0
Hemiparaesthesia	3	0
Hyperaesthesia	86	0
Hypoaesthesia	2722	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Paraesthesia	3734	0
Reversed hot-cold sensation	4	0
Synaesthesia	1	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Diplegia	12	0
Hemiparesis	45	0
Hemiplegia	37	0
Locked-in syndrome	1	0
Monoparesis	58	0
Monoplegia	74	0
Paralysis	121	0
Paraparesis	3	0
Paraplegia	1	0
Paresis	6	0
Quadriparesis	1	0
Quadriplegia	1	0
<i>Parkinson's disease and parkinsonism</i>		
Freezing phenomenon	8	0
Hypokinetic dysarthria	1	0
Parkinson's disease	3	0
Parkinsonian gait	1	0
Parkinsonian rest tremor	1	0
Parkinsonism	4	0
Reduced facial expression	11	0
<i>Partial complex seizures</i>		
Dreamy state	6	0
Focal dyscognitive seizures	3	0
Temporal lobe epilepsy	2	0
<i>Partial simple seizures NEC</i>		
Autonomic seizure	1	0
<i>Peripheral neuropathies NEC</i>		
Axonal neuropathy	2	0
Neuralgic amyotrophy	5	0
Neuritis	7	0
Neuropathy peripheral	106	0
Peripheral sensorimotor neuropathy	1	0
Peripheral sensory neuropathy	12	0
Polyneuropathy	3	0
Thoracic outlet syndrome	1	0
<i>Seizures and seizure disorders NEC</i>		
Atonic seizures	5	0
Change in seizure presentation	2	0
Clonic convulsion	3	0
Convulsions local	1	0
Epilepsy	153	0
Epileptic aura	2	0
Epileptic encephalopathy	1	0
Febrile convulsion	15	0
Idiopathic generalised epilepsy	1	0
Partial seizures	19	0
Post stroke seizure	1	0
Psychogenic seizure	8	0
Seizure	571	1

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Seizure anoxic	2	0
Seizure cluster	6	0
Seizure like phenomena	2	0
Status epilepticus	43	0
Tonic clonic movements	3	0
Tonic convulsion	26	0
Tonic posturing	1	0
Sensory abnormalities NEC		
Ageusia	490	0
Allodynia	24	0
Aura	21	0
Complex regional pain syndrome	5	0
Dysgeusia	1087	0
Electric shock sensation	36	0
Hypergeusia	1	0
Hypogeusia	7	0
Intercostal neuralgia	1	0
Loss of proprioception	3	0
Morton's neuralgia	1	0
Neuralgia	502	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	134	0
Sensory disturbance	100	0
Sensory loss	71	0
Taste disorder	243	0
Visual perseveration	3	0
Sleep disturbances NEC		
Sleep deficit	9	0
Sudden onset of sleep	1	0
Speech and language abnormalities		
Dysarthria	181	0
Incoherent	9	0
Language disorder	2	0
Repetitive speech	3	0
Slow speech	18	0
Speech disorder	65	0
Spinal cord and nerve root disorders NEC		
Cauda equina syndrome	1	0
Myelopathy	1	0
Radiculitis brachial	12	0
Radiculopathy	5	0
Structural brain disorders NEC		
Brain injury	7	2
Cerebral ventricle dilatation	1	0
Hyperintensity in brain deep nuclei	1	0
Transient cerebrovascular events		
Transient ischaemic attack	140	3
Tremor (excl congenital)		
Essential tremor	4	0
Head titubation	13	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Resting tremor	4	0
Tremor	1592	0
<i>Trigeminal disorders</i>		
Numb chin syndrome	2	0
Trigeminal nerve disorder	3	0
Trigeminal neuralgia	58	0
Trigeminal neuritis	2	0
<i>Vagus nerve disorders</i>		
Vocal cord paralysis	1	0
<i>Vertigos NEC</i>		
Cervicogenic vertigo	1	0
Vertigo CNS origin	3	0
Nervous system disorders SOC TOTAL	62659	62

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortion related conditions and complications</i>		
Anembryonic gestation	2	0
<i>Abortions not specified as induced or spontaneous</i>		
Abortion	1	0
Abortion missed	5	0
<i>Abortions spontaneous</i>		
Abortion spontaneous	368	0
Abortion threatened	2	0
<i>Amniotic fluid and cavity disorders of pregnancy NEC</i>		
Amniorrhoea	1	0
<i>Foetal complications NEC</i>		
Foetal cardiac disorder	1	0
Foetal distress syndrome	1	0
Foetal hypokinesia	10	0
<i>Foetal growth complications</i>		
Foetal growth restriction	6	0
<i>Gestational age and weight conditions</i>		
Premature baby	4	1
<i>Haemorrhagic complications of pregnancy</i>		
Haemorrhage in pregnancy	2	0
Premature separation of placenta	3	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>		
Induced labour	1	0
Premature delivery	1	0
Premature labour	5	0
Premature rupture of membranes	2	0
Threatened labour	1	0
<i>Maternal complications of delivery NEC</i>		
Retained placenta or membranes	2	0
<i>Maternal complications of labour NEC</i>		
Uterine contractions abnormal	1	0
Uterine hypertonus	8	0
<i>Maternal complications of pregnancy NEC</i>		
Biochemical pregnancy	1	0
Complication of pregnancy	1	0
Decidual cast	4	0
Ectopic pregnancy	8	0
Hyperemesis gravidarum	1	0
Morning sickness	15	0
Preterm premature rupture of membranes	3	0
Ruptured ectopic pregnancy	1	0
Somatic symptom disorder of pregnancy	3	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	4	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Pregnancy conditions <small>Pregnancy conditions cont'd</small>		
Pregnancy	33	0
Uterine contractions during pregnancy	5	0
<i>Placental abnormalities (excl neoplasms)</i>		
Placental disorder	1	0
Placental insufficiency	1	0
<i>Postpartum complications NEC</i>		
Postpartum haemorrhage	3	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	2	0
Peripartum cardiomyopathy	1	0
<i>Stillbirth and foetal death</i>		
Foetal death	3	3
Stillbirth	7	7
<i>Unintended pregnancies</i>		
Pregnancy after post coital contraception	2	0
Pregnancy on contraceptive	2	0
Pregnancy on oral contraceptive	2	0
Pregnancy with contraceptive device	1	0
Pregnancy with implant contraceptive	1	0
Unintended pregnancy	2	0
Unwanted pregnancy	1	0
Pregnancy conditions SOC TOTAL	542	11

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

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	12	0
<i>Device physical property and chemical issues</i>		
Device breakage	1	0
Device defective	7	0
Device kink	1	0
Needle issue	3	0
<i>Product contamination and sterility issues</i>		
Product contamination	11	0
Product contamination physical	6	0
<i>Product packaging issues</i>		
Product closure issue	1	0
<i>Product physical issues</i>		
Liquid product physical issue	9	0
Product after taste	2	0
Product deposit	1	0
Product odour abnormal	2	0
Product physical issue	2	0
Product taste abnormal	10	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	99	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	25	0
Behaviour disorder	1	0
Breath holding	6	0
Staring	7	0
<i>Adjustment disorders</i>		
Adjustment disorder with depressed mood	4	0
<i>Affect alterations NEC</i>		
Affect lability	12	0
Constricted affect	3	0
Flat affect	11	0
Inappropriate affect	22	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	74	0
Anxiety	796	0
Immunisation anxiety related reaction	2	0
Nervousness	168	0
Stress	96	0
Tension	38	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	6	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	13	0
Attention-seeking behaviour	1	0
Aversion	1	0
Disinhibition	2	0
Indifference	6	0
Paranoia	24	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	200	0
<i>Communications disorders</i>		
Communication disorder	5	0
Mutism	3	0
<i>Confusion and disorientation</i>		
Confusional state	829	0
Disorientation	272	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: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Deliria</i>		
Delirium	105	0
<i>Delusional symptoms</i>		
Delusion	11	0
<i>Depressive disorders</i>		
Agitated depression	5	0
Depression	319	0
Depression suicidal	14	0
Major depression	9	0
Mixed anxiety and depressive disorder	3	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	11	0
Dissociation	29	0
Dissociative amnesia	2	0
Dissociative disorder	2	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	22	0
Insomnia	1366	0
Middle insomnia	27	0
Terminal insomnia	32	0
<i>Dyssomnias</i>		
Breathing-related sleep disorder	1	0
Dyssomnia	1	0
Poor quality sleep	210	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	35	0
Dysphoria	2	0
Emotional disorder	54	0
Emotional distress	41	0
Emotional poverty	1	0
Euphoric mood	42	0
Frustration tolerance decreased	2	0
Irritability	194	0
Mood altered	53	0
<i>Factitious disorders</i>		
Factitious disorder	4	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Agoraphobia	2	0
Fear	18	0
Fear of death	1	0
Fear of eating	1	0
Fear of falling	3	0
Fear of injection	7	0
Osmophobia	1	0
Phobia	3	0
Phonophobia	2	0
Social anxiety disorder	1	0
Social fear	1	0
<i>Fluctuating mood symptoms</i>		

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Mood swings	137	0
Hallucinations (excl sleep-related)		
Hallucination	192	0
Hallucination, auditory	14	0
Hallucination, olfactory	11	0
Hallucination, tactile	1	0
Hallucination, visual	25	0
Hallucinations, mixed	2	0
Increased physical activity levels		
Restlessness	144	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	15	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	367	0
Depressive symptom	2	0
Feeling guilty	1	0
Feeling of despair	5	0
Feelings of worthlessness	1	0
Negative thoughts	1	0
Psychomotor retardation	2	0
Sense of a foreshortened future	3	0
Tearfulness	40	0
Mood alterations with manic symptoms		
Hypomania	2	0
Mania	11	0
Mood disorders NEC		
Affective disorder	3	0
Apathy	28	0
Boredom	1	0
Laziness	3	0
Listless	19	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

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Panic attacks and disorders</i>		
Panic attack	184	0
Panic disorder	3	0
Panic reaction	28	0
<i>Paraphilias and paraphilic disorders</i>		
Transvestism	1	0
<i>Parasomnias</i>		
Abnormal dreams	170	0
Abnormal sleep-related event	1	0
Confusional arousal	1	0
Exploding head syndrome	2	0
Nightmare	187	0
Parasomnia	2	0
Sleep inertia	1	0
Sleep talking	6	0
Sleep terror	21	0
Somnambulism	6	0
<i>Perception disturbances NEC</i>		
Autoscopy	17	0
Deja vu	2	0
Derealisation	8	0
Flashback	3	0
Illusion	2	0
Near death experience	1	0
Time perception altered	2	0
<i>Personality disorders NEC</i>		
Personality disorder	1	0
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	2	0
<i>Psychiatric elimination disorders</i>		
Enuresis	21	0
<i>Psychiatric symptoms NEC</i>		
Helplessness	1	0
Hypervigilance	9	0
Psychiatric symptom	5	0
Psychological trauma	3	0
Trance	1	0
<i>Psychotic disorder NEC</i>		
Acute psychosis	1	0
Psychotic behaviour	1	0
Psychotic disorder	23	0
<i>Schizophrenia NEC</i>		
Schizophrenia	1	0
<i>Sexual and gender identity disorders NEC</i>		
Gender dysphoria	1	0
<i>Sexual arousal disorders</i>		
Disturbance in sexual arousal	3	0
Sexual inhibition	1	0
<i>Sexual desire disorders</i>		
Hypersexuality	1	0
Libido decreased	14	0
Libido increased	6	0
Loss of libido	16	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Sexual dysfunction NEC</i>		
Genito-pelvic pain/penetration disorder	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	197	0
Sleep disorder due to general medical condition, insomnia type	5	0
<i>Somatic symptom disorders</i>		
Conversion disorder	21	0
Habit cough	16	0
Somatic symptom disorder	1	0
Vomiting psychogenic	1	0
<i>Speech and language usage disturbances</i>		
Disorganised speech	7	0
Logorrhoea	2	0
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	24	0
Lack of spontaneous speech	1	0
Pressure of speech	1	0
<i>Stereotypies and automatisms</i>		
Automatism	1	0
Bruxism	11	0
Head banging	10	0
Stereotypy	1	0
<i>Stress disorders</i>		
Burnout syndrome	2	0
Post-traumatic stress disorder	4	0
<i>Substance related and addictive disorders</i>		
Alcohol problem	1	0
Alcoholic hangover	1	0
Alcoholism	3	0
Nicotine dependence	2	0
<i>Suicidal and self-injurious behaviour</i>		
Completed suicide	1	1
Intentional self-injury	6	0
Self-injurious ideation	2	0
Suicidal ideation	36	0
Suicide attempt	8	0
Suicide threat	1	0
<i>Thinking disturbances</i>		
Bradyphrenia	39	0
Intrusive thoughts	7	0
Morbid thoughts	1	0
Tachyphrenia	5	0
Thinking abnormal	19	0
Thought blocking	1	0
<i>Tic disorders</i>		
Tic	10	0
Psychiatric disorders SOC TOTAL	7588	1

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	2	0
Bladder irritation	8	0
Bladder pain	28	0
Dysuria	46	0
Incontinence	26	0
Lower urinary tract symptoms	3	0
Micturition disorder	2	0
Micturition urgency	39	0
Pollakiuria	122	0
Stress urinary incontinence	1	0
Urethral pain	7	0
Urge incontinence	1	0
Urinary hesitation	1	0
Urinary incontinence	49	0
Urinary retention	37	0
Urine flow decreased	14	0
<i>Bladder disorders NEC</i>		
Bladder disorder	8	0
Bladder fibrosis	1	0
Bladder prolapse	1	0
Urinary bladder haemorrhage	2	0
<i>Bladder infections and inflammations</i>		
Cystitis interstitial	5	0
Cystitis noninfective	1	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	2	0
IgA nephropathy	3	0
Nephrotic syndrome	17	0
<i>Myoneurogenic bladder disorders</i>		
Bladder dysfunction	5	0
Hypertonic bladder	1	0
Hypotonic urinary bladder	1	0
Loss of bladder sensation	2	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	5	1
Renal haemorrhage	1	0
Renal mass	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	46	4
Anuria	3	0
Chronic kidney disease	4	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Renal & urinary disorders cont'd</i>		
Oliguria	1	0
Renal failure	19	1
Renal impairment	23	0
Renal injury	2	0
<i>Renal lithiasis</i>		
Nephrolithiasis	9	0
<i>Renal neoplasms</i>		
Renal cyst	1	0
<i>Renal obstructive disorders</i>		
Hydronephrosis	2	0
<i>Renal structural abnormalities and trauma</i>		
Kidney small	1	0
<i>Renal vascular and ischaemic conditions</i>		
Renal infarct	1	0
Renal tubular necrosis	1	0
Renal vasculitis	1	1
<i>Structural and obstructive urethral disorders (excl congenital)</i>		
Urethral stenosis	1	0
<i>Ureteric disorders NEC</i>		
Ureteric stenosis	1	0
<i>Urinary abnormalities</i>		
Albuminuria	1	0
Chromaturia	46	0
Haematuria	34	0
Ketonuria	1	0
Myoglobinuria	1	0
Proteinuria	11	0
Urine abnormality	11	0
Urine odour abnormal	8	0
<i>Urinary tract lithiasis (excl renal)</i>		
Calculus urinary	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Costovertebral angle tenderness	1	0
Cystitis-like symptom	1	0
Haemorrhage urinary tract	21	0
Nocturia	3	0
Polyuria	8	0
Renal colic	4	0
Renal pain	259	0
Urinary tract discomfort	1	0
Urinary tract pain	5	0
Renal & urinary disorders SOC TOTAL	993	7

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	13	0
<i>Breast disorders NEC</i>		
Breast disorder	1	0
Breast enlargement	26	0
Breast mass	106	0
Gynaecomastia	4	0
Mastoptosis	1	0
Nipple disorder	1	0
<i>Breast infections and inflammations</i>		
Breast inflammation	2	0
Nipple inflammation	2	0
<i>Breast signs and symptoms</i>		
Breast discharge	4	0
Breast discomfort	10	0
Breast engorgement	9	0
Breast haematoma	1	0
Breast oedema	5	0
Breast pain	610	0
Breast swelling	132	0
Breast tenderness	73	0
Nipple pain	37	1
Nipple swelling	4	0
<i>Cervix disorders NEC</i>		
Cervical dysplasia	2	0
Cervix disorder	1	0
Cervix haemorrhage uterine	5	0
Ectropion of cervix	2	0
<i>Cervix infections and inflammations</i>		
Cervix inflammation	1	0
<i>Cervix neoplasms</i>		
Cervical polyp	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation disorder	2	0
Ejaculation failure	3	0
Erectile dysfunction	57	0
Erection increased	2	0
Organic erectile dysfunction	14	0
Painful ejaculation	1	0
Spontaneous ejaculation	1	0
Spontaneous penile erection	1	0
<i>Fallopian tube and ovary infections and inflammations</i>		
Noninfective oophoritis	3	0
<i>Lactation disorders</i>		
Breast milk discolouration	3	0
Breast milk odour abnormal	2	0
Galactorrhoea	5	0
Galactostasis	1	0
Lactation disorder	6	0
Lactation puerperal increased	5	0
Suppressed lactation	42	0
<i>Menopausal effects NEC</i>		
Artificial menopause	1	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Menopausal disorder	1	0
Menopausal symptoms	25	0
Menopause delayed	1	0
Premature menopause	15	0
<i>Menopausal effects on the genitourinary tract</i>		
Atrophic vulvovaginitis	1	0
Postmenopausal haemorrhage	85	0
<i>Menstruation and uterine bleeding NEC</i>		
Abnormal uterine bleeding	6	0
Abnormal withdrawal bleeding	1	0
Dysmenorrhoea	2614	0
Intermenstrual bleeding	991	0
Menstrual discomfort	25	0
Menstrual disorder	1667	0
Menstruation irregular	2946	0
Premenstrual dysphoric disorder	10	0
Premenstrual headache	10	0
Premenstrual pain	106	0
Premenstrual syndrome	101	0
Retrograde menstruation	1	0
Withdrawal bleed	15	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	535	0
Hypomenorrhoea	598	0
Menstruation delayed	4481	0
Oligomenorrhoea	142	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	4940	0
Menometrorrhagia	17	0
Polymenorrhoea	769	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Haemorrhagic ovarian cyst	1	0
Ovarian cyst	19	0
Ovarian cyst ruptured	1	0
Polycystic ovaries	43	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Adnexal torsion	1	0
Hydrosalpinx	2	0
Ovarian enlargement	1	0
Ovarian haemorrhage	6	0
Ovulation disorder	2	0
Ovulation pain	60	0
Premature ovulation	4	0
<i>Pelvic prolapse conditions</i>		
Vaginal prolapse	1	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri mass	1	0
Adnexa uteri pain	46	0
Pelvic congestion	1	0
Pelvic floor muscle weakness	1	0
Pelvic haemorrhage	17	0
<i>Penile and scrotal infections and inflammations</i>		
Balanoposthitis	2	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile blister	1	0
Penile discharge	1	0
Penile discomfort	1	0
Penile erythema	1	0
Penile haemorrhage	3	0
Penile pain	1	0
Penile size reduced	1	0
Penile swelling	5	0
Penis disorder	9	0
<i>Prostate and seminal vesicles infections and inflammations</i>		
Prostatitis	3	0
<i>Prostatic signs, symptoms and disorders NEC</i>		
Prostatic pain	1	0
Prostatomegaly	3	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Genital erosion	1	0
Genital haemorrhage	23	0
Genital hypoaesthesia	1	0
Genital lesion	2	0
Genital paraesthesia	1	0
Genital ulceration	6	0
Perineal ulceration	1	0
<i>Reproductive tract infections and inflammations NEC</i>		
Genital tract inflammation	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital burning sensation	2	0
Genital erythema	1	0
Genital pain	5	0
Genital rash	4	0
Genital swelling	3	0
Pelvic discomfort	5	0
Pelvic pain	94	0
Perineal pain	2	0
Perineal rash	1	0
Pruritus genital	4	0
<i>Scrotal disorders NEC</i>		
Acquired hydrocele	1	0
Scrotal angiokeratoma	1	0
Scrotal discomfort	1	0
Scrotal erythema	1	0
Scrotal exfoliation	1	0
Scrotal pain	22	0
Scrotal swelling	4	0
Varicocele	1	0
<i>Sexual function and fertility disorders NEC</i>		
Dyspareunia	5	0
Infertility	9	0
Infertility female	2	0
Sexual dysfunction	6	0
<i>Spermatogenesis and semen disorders</i>		
Aspermia	1	0
Haematospermia	6	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Semen discolouration	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular disorder	3	0
Testicular pain	51	0
Testicular swelling	8	0
Testis discomfort	2	0
<i>Uterine disorders NEC</i>		
Adenomyosis	7	0
Endometrial thickening	3	0
Endometriosis	78	0
Uterine haemorrhage	34	0
Uterine pain	14	0
<i>Uterine infections and inflammations (excl cervix)</i>		
Uterine inflammation	1	0
<i>Uterine neoplasms</i>		
Uterine polyp	4	0
<i>Uterine tone disorders</i>		
Uterine spasm	29	0
<i>Vulvovaginal cysts and neoplasms</i>		
Bartholin's cyst	1	0
Vaginal cyst	6	0
Vaginal polyp	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	1401	0
Vaginal mucosal blistering	1	0
Vaginal ulceration	1	0
Vulval disorder	1	0
Vulval haemorrhage	25	0
Vulval ulceration	7	0
Vulvovaginal ulceration	4	0
<i>Vulvovaginal signs and symptoms</i>		
Clitoral engorgement	1	0
Coital bleeding	5	0
Labia enlarged	1	0
Vaginal discharge	71	0
Vaginal lesion	1	0
Vaginal odour	2	0
Vulval oedema	1	0
Vulvovaginal burning sensation	4	0
Vulvovaginal dryness	5	0
Vulvovaginal erythema	1	0
Vulvovaginal pain	25	0
Vulvovaginal pruritus	8	0
Vulvovaginal rash	2	0
Vulvovaginal swelling	4	0
Reproductive & breast disorders SOC TOTAL	23576	1

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	5	0
Apnoeic attack	1	0
Dyspnoea	4237	5
Dyspnoea at rest	11	0
Dyspnoea exertional	35	1
Grunting	1	0
Hyperventilation	46	0
Hypopnoea	102	0
Hypoventilation	1	0
Irregular breathing	19	0
Mouth breathing	4	0
Nocturnal dyspnoea	2	0
Orthopnoea	3	0
Respiration abnormal	49	0
Respiratory arrest	14	0
Respiratory depression	1	0
Respiratory distress	17	0
Sleep apnoea syndrome	12	0
Tachypnoea	25	0
<i>Bronchial conditions NEC</i>		
Bronchial secretion retention	4	0
Bronchiectasis	12	0
<i>Bronchospasm and obstruction</i>		
Asthma	326	0
Asthma late onset	2	0
Bronchospasm	15	0
Chronic obstructive pulmonary disease	16	1
Cough variant asthma	5	0
Obstructive airways disorder	9	0
Reversible airways obstruction	1	0
Wheezing	371	0
<i>Conditions associated with abnormal gas exchange</i>		
Asphyxia	2	0
Cyanosis central	1	0
Hyperoxia	1	0
Hypoxia	28	2
Respiratory acidosis	2	0
<i>Coughing and associated symptoms</i>		
Allergic cough	7	0
Cough	2256	3
Cough decreased	2	0
Haemoptysis	53	0
Productive cough	154	0
Sputum discoloured	7	0
Sputum increased	3	0
<i>Diaphragmatic disorders</i>		
Acquired diaphragmatic eventration	1	0
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

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Vocal cord disorder	1	0
Vocal cord dysfunction	2	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Epiglottic oedema	1	0
Laryngeal obstruction	1	0
Laryngeal oedema	2	0
Laryngospasm	1	0
Stridor	22	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Alveolitis	1	0
Hypersensitivity pneumonitis	1	0
Lower respiratory tract inflammation	1	0
Pneumonitis	27	1
Pulmonary sarcoidosis	2	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	29	0
Increased bronchial secretion	2	0
Increased viscosity of bronchial secretion	1	0
Lung hyperinflation	1	0
Lung opacity	2	0
Pleuritic pain	20	0
Pulmonary haemorrhage	1	0
Pulmonary pain	79	0
Rales	4	0
Respiratory fremitus	1	0
<i>Mediastinal disorders</i>		
Mediastinal mass	1	0
Pulmonary hilum mass	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	259	0
Nasal inflammation	3	0
Rhinitis allergic	18	0
<i>Nasal disorders NEC</i>		
Epistaxis	833	0
Intranasal hyposaesthesia	2	0
Intranasal paraesthesia	1	0
Nasal crusting	2	0
Nasal disorder	3	0
Nasal dryness	34	0
Nasal mucosal discolouration	1	0
Nasal odour	6	0
Nasal oedema	6	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	3	0
Sinonasal obstruction	9	0
Sinus congestion	57	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Sinus disorder	6	0
<i>Parenchymal lung disorders NEC</i>		
Atelectasis	3	0
Combined pulmonary fibrosis and emphysema	1	0
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	5	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Hyperactive pharyngeal reflex	1	0
Pharyngeal enanthema	1	0
Pharyngeal erythema	7	0
Pharyngeal haemorrhage	2	0
Pharyngeal hypoaesthesia	34	0
Pharyngeal inflammation	4	0
Pharyngeal mass	1	0
Pharyngeal oedema	13	0
Pharyngeal paraesthesia	51	0
Pharyngeal swelling	232	0
Pharyngeal ulceration	14	0
Tonsillar erythema	10	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	78	0
Tonsillar inflammation	3	0
Tonsillar ulcer	1	0
Tonsillolith	1	0
<i>Pleural infections and inflammations</i>		
Pleurisy	31	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	24	0
Pneumothorax	8	0
Pneumothorax spontaneous	3	0
<i>Pulmonary hypertensions</i>		
Pulmonary hypertension	2	0
<i>Pulmonary oedemas</i>		
Acute respiratory distress syndrome	2	1
Pulmonary congestion	12	0
Pulmonary oedema	20	1
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary artery thrombosis	1	0
Pulmonary embolism	407	29
Pulmonary infarction	6	0
Pulmonary thrombosis	7	1
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	2	1
Respiratory failure	11	2
<i>Respiratory signs and symptoms NEC</i>		
Allergic respiratory symptom	6	0
Diaphragmalgia	7	0
Nasal flaring	1	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Painful respiration	10	1
Pleural rub	1	0
Respiratory symptom	18	0
Suffocation feeling	2	0
<i>Respiratory tract disorders NEC</i>		
Aspiration	2	0
Lung disorder	6	0
Pulmonary mass	4	0
Respiratory disorder	13	1
Respiratory tract congestion	3	0
Respiratory tract haemorrhage	1	0
Respiratory tract inflammation	2	0
Respiratory tract irritation	9	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	105	0
Catarrh	23	0
Choking	14	0
Choking sensation	3	0
Dry throat	160	0
Dysphonia	151	0
Increased upper airway secretion	5	0
Increased viscosity of upper respiratory secretion	31	0
Nasal discharge discolouration	3	0
Nasal discomfort	44	0
Nasal obstruction	2	0
Oropharyngeal blistering	9	0
Oropharyngeal discomfort	59	0
Oropharyngeal pain	2643	0
Oropharyngeal plaque	2	0
Paranasal sinus discomfort	42	0
Rhinalgia	11	0
Rhinorrhoea	843	0
Sinus pain	196	0
Sneezing	345	0
Snoring	7	0
Throat clearing	8	0
Throat irritation	217	0
Throat tightness	244	0
Upper airway obstruction	2	0
Upper respiratory tract congestion	2	0
Upper respiratory tract irritation	1	0
Upper-airway cough syndrome	9	0
Yawning	25	0
<i>Vascular pulmonary disorders NEC</i>		
Acute chest syndrome	1	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Respiratory disorders SOC TOTAL	15641	50

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	178	0
Acne cystic	20	0
Dermatitis acneiform	10	0
<i>Alopecias</i>		
Alopecia	249	0
Alopecia areata	40	0
Alopecia totalis	2	0
Androgenetic alopecia	2	0
Diffuse alopecia	4	0
Hypotrichosis	1	0
Lichen planopilaris	1	0
Madarosis	3	0
<i>Angioedemas</i>		
Angioedema	195	0
Circumoral swelling	1	0
<i>Apocrine and eccrine gland disorders</i>		
Anhidrosis	1	0
Bromhidrosis	1	0
Cold sweat	706	0
Hidradenitis	4	0
Hyperhidrosis	2016	0
Hypohidrosis	2	0
Milia	2	0
Miliaria	84	0
Night sweats	562	0
<i>Bullous conditions</i>		
Blister	424	0
Blister rupture	1	0
Blood blister	25	0
Dermatitis bullous	11	0
Erythema multiforme	36	0
Fracture blisters	1	0
Herpes gestationis	1	0
Pemphigoid	23	0
Pemphigus	7	0
Stevens-Johnson syndrome	5	0
Toxic epidermal necrolysis	2	1
<i>Connective tissue disorders</i>		
Cutaneous lupus erythematosus	1	0
Dermatomyositis	7	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	204	0
Koebner phenomenon	1	0
Macule	5	0
Neutrophilic dermatosis	1	0
Pain of skin	247	0
Papule	100	0
Pathergy reaction	1	0
Scab	21	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Scar pain	12	0
Sensitive skin	159	0
Shagreen skin	1	0
Skin burning sensation	198	0
Skin degenerative disorder	1	0
Skin discolouration	127	0
Skin discomfort	5	0
Skin disorder	24	0
Skin fissures	8	0
Skin indentation	2	0
Skin induration	4	0
Skin lesion	42	0
Skin lesion inflammation	1	0
Skin necrosis	2	0
Skin odour abnormal	19	0
Skin plaque	3	0
Skin reaction	129	0
Skin sensitisation	37	0
Skin swelling	82	0
Skin texture abnormal	2	0
Skin tightness	26	0
Skin warm	277	0
Skin weeping	11	0
Sticky skin	2	0
Target skin lesion	2	0
Transient acantholytic dermatosis	1	0
Yellow skin	25	0
<i>Dermatitis and eczema</i>		
Dermatitis	121	0
Dermatitis allergic	213	0
Dermatitis atopic	36	0
Dermatitis contact	18	0
Dermatitis diaper	3	0
Dyshidrotic eczema	26	0
Eczema	291	0
Eczema asteatotic	9	0
Eczema infantile	1	0
Eczema nummular	5	0
Eczema weeping	1	0
Hand dermatitis	1	0
Intertrigo	1	0
Perioral dermatitis	2	0
Seborrhoeic dermatitis	4	0
Skin irritation	109	0
Stasis dermatitis	1	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	30	0
Drug reaction with eosinophilia and systemic symptoms	1	0
Fixed eruption	2	0
Palmar-plantar erythrodysesthesia syndrome	1	0
Toxic skin eruption	2	0
<i>Erythemas</i>		
Erythema	1982	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Palmar erythema	4	0
Red man syndrome	2	0
Exfoliative conditions		
Dermatitis exfoliative	2	0
Dermatitis exfoliative generalised	5	0
Exfoliative rash	20	0
Keratolysis exfoliativa acquired	2	0
Skin exfoliation	111	0
Granulomatous and deep cutaneous inflammatory conditions		
Cutaneous sarcoidosis	1	0
Granuloma annulare	5	0
Hyperkeratoses		
Hyperkeratosis	1	0
Keratosis pilaris	3	0
Lichenoid keratosis	3	0
Hyperpigmentation disorders		
Argyria	1	0
Chloasma	1	0
Ephelides	1	0
Skin hyperpigmentation	5	0
Solar lentigo	2	0
Hypertrichoses		
Hirsutism	2	0
Hypopigmentation disorders		
Skin depigmentation	4	0
Skin hypopigmentation	1	0
Vitiligo	18	0
Lipodystrophies		
Lipoatrophy	4	0
Lipodystrophy acquired	1	0
Nail and nail bed conditions (excl infections and infestations)		
Nail discolouration	10	0
Nail disorder	2	0
Nail pigmentation	2	0
Nail ridging	3	0
Onychalgia	8	0
Onychoclasia	5	0
Onychomadesis	2	0
Splinter haemorrhages	3	0
Panniculitides		
Erythema nodosum	24	0
Panniculitis	1	0
Papulosquamous conditions		
Erythema annulare	2	0
Lichen planus	16	0
Lichen sclerosus	9	0
Parapsoriasis	2	0
Pityriasis rosea	108	0
Photosensitivity and photodermatosis conditions		
Photosensitivity reaction	60	0
Polymorphic light eruption	2	0
Solar dermatitis	1	0
Pigmentation changes NEC		

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Haemosiderin stain	1	0
Pigmentation disorder	13	0
<i>Pilar disorders NEC</i>		
Hair colour changes	10	0
Hair disorder	1	0
Hair growth abnormal	5	0
Hair texture abnormal	5	0
Piloerection	25	0
Pseudofolliculitis	3	0
Trichorrhexis	2	0
<i>Pruritus NEC</i>		
Itching scar	5	0
Pruritus	4874	0
<i>Psoriatic conditions</i>		
Dermatitis psoriasiform	3	0
Guttate psoriasis	14	0
Nail psoriasis	1	0
Palmoplantar pustulosis	2	0
Psoriasis	169	0
Pustular psoriasis	2	0
Rebound psoriasis	1	0
<i>Purpura and related conditions</i>		
Ecchymosis	1	0
Henoch-Schonlein purpura	9	0
Petechiae	135	0
Purpura	51	0
<i>Pustular conditions</i>		
Acute generalised exanthematous pustulosis	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Butterfly rash	4	0
Rash	5146	1
Rash erythematous	1081	0
Rash macular	467	0
Rash maculo-papular	58	0
Rash morbilliform	42	0
Rash papular	314	0
Rash pruritic	1087	0
Rash vesicular	70	0
Systemic lupus erythematosus rash	7	0
<i>Rosaceas</i>		
Rosacea	27	0
<i>Scaly conditions</i>		
Dandruff	4	0
Pityriasis	22	0
<i>Sebaceous gland disorders</i>		
Seborrhoea	10	0
<i>Skin and subcutaneous conditions NEC</i>		
Cellulite	2	0
Cutaneous symptom	5	0
Reactive perforating collagenosis	1	0
Skin mass	19	0
<i>Skin and subcutaneous tissue ulcerations</i>		
Ischaemic skin ulcer	1	0

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Mucocutaneous ulceration	1	0
Pyoderma gangrenosum	1	0
Scleroderma associated digital ulcer	1	0
Skin erosion	23	0
Skin ulcer	18	0
Skin cysts and polyps		
Dermal cyst	13	0
Skin dystrophies		
Keloid scar	3	0
Skin wrinkling	2	0
Skin haemorrhages		
Haemorrhage subcutaneous	10	0
Skin haemorrhage	18	0
Skin hyperplasias and hypertrophies		
Skin hypertrophy	2	0
Skin hypoplasias and atrophies		
Skin atrophy	2	0
Skin striae	7	0
Skin injuries and mechanical dermatoses		
Decubitus ulcer	2	0
Needle track marks	4	0
Skin preneoplastic conditions NEC		
Actinic keratosis	1	0
Skin vascular conditions NEC		
Skin oedema	4	0
Skin vasculitides		
Capillaritis	2	0
Cutaneous vasculitis	13	0
Hypersensitivity vasculitis	1	0
Vasculitic rash	19	0
Skin vasomotor conditions		
Livedo reticularis	21	0
Telangiectasia and related conditions		
Spider naevus	1	0
Telangiectasia	1	0
Urticarias		
Chronic spontaneous urticaria	7	0
Cold urticaria	6	0
Idiopathic urticaria	1	0
Mechanical urticaria	8	0
Solar urticaria	2	0
Urticaria	1687	0
Urticaria cholinergic	1	0
Urticaria chronic	17	0
Urticaria contact	1	0
Urticaria papular	4	0
Urticaria thermal	6	0
Urticularial vasculitis	3	0
Skin disorders SOC TOTAL	25345	2

Case Series Drug Analysis Print

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

Report Run Date: 05-Nov-2021

Data Lock Date: 03-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Infant	3	0
Menarche	2	0
Menopause	36	0
Postmenopause	3	0
<i>Alcohol product use</i>		
Alcoholic	1	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	24	0
Blood product transfusion dependent	1	0
Breast prosthesis user	3	0
Disability	2	0
Hearing disability	1	0
Housebound	1	0
Immobile	13	0
Impaired driving ability	4	0
Impaired work ability	11	0
Loss of personal independence in daily activities	38	0
Physical disability	5	0
Sight disability	10	0
Sitting disability	3	0
Walking disability	1	0
Wheelchair user	1	0
<i>Economic circumstances</i>		
High income	1	0
Low income	1	0
<i>Educational issues</i>		
Educational problem	1	0
Illiteracy	1	0
<i>Employment issues</i>		
Job dissatisfaction	1	0
Retirement	4	0
Stress at work	2	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>		
Exercise adequate	1	0
Hair dye user	2	0
Impaired quality of life	3	0
<i>Tobacco use</i>		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Social circumstances Social circumstances cont'd		
Ex-tobacco user	1	0
Non-tobacco user	3	0
Tobacco user	1	0
Social circumstances SOC TOTAL	212	0

Case Series Drug Analysis Print

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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 prophylaxis	1	0
COVID-19 treatment	3	0
<i>Arterial therapeutic procedures (excl aortic)</i>		
Splenic artery embolisation	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 device therapeutic procedures</i>		
Cardiac pacemaker insertion	1	0
<i>Cardiac therapeutic procedures NEC</i>		
Cardiac operation	1	0
<i>Contraceptive methods female</i>		
Contraception	1	0
Contraceptive implant	3	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	9	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	16	0
<i>Gynaecological therapeutic procedures NEC</i>		
Menstrual cycle management	13	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	8	0
Oestrogen replacement therapy	1	0
<i>Immunisations</i>		
COVID-19 immunisation	97	0
Immunisation	91	1

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Reaction Name	Total	Fatal
Surgical & medical procedures		
Surgical & medical procedures cont'd		
Influenza immunisation	2	0
Induced abortions		
Abortion induced	2	0
Joint therapeutic procedures		
Joint injection	3	0
Joint surgery	1	0
Knee arthroplasty	1	0
Large intestine therapeutic procedures		
Appendectomy	4	0
Limb therapeutic procedures		
Arm amputation	1	0
Limb immobilisation	8	0
Limb operation	6	0
Lymphoid tissue therapeutic procedures		
Lymphadenectomy	2	0
Splenectomy	1	0
Mastectomies		
Breast conserving surgery	4	0
Nail therapeutic procedures		
Nail operation	3	0
Nervous system therapeutic procedures NEC		
Multiple sclerosis relapse prophylaxis	2	0
Obstetric therapeutic procedures		
Caesarean section	1	0
Labour stimulation	1	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	5	0
Therapeutic skin care topical	1	0
Skull and brain therapeutic procedures		
Cerebrovascular operation	1	0
Posterior fossa decompression	1	0
Therapeutic bladder catheterisation		
Bladder catheterisation	2	0

Case Series Drug Analysis Print

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Surgical & medical procedures		
<i>Surgical & medical procedures cont'd</i>		
<i>Therapeutic procedures NEC</i>		
Abscess drainage	1	0
Anaphylaxis treatment	6	0
Bed rest	2	0
Fatigue management	1	0
Hospitalisation	11	0
Injection	45	0
Interchange of vaccine products	19	0
Localised alternating hot and cold therapy	2	0
Magnetic therapy	1	0
Mass excision	3	0
Medical procedure	1	0
Medication dilution	2	0
Physical fitness training	1	0
Product used for unknown indication	2	0
Promotion of wound healing	1	0
Specialist consultation	1	0
Stent placement	1	0
Therapeutic procedure	1	0
Therapy change	1	0
<i>Tracheal therapeutic procedures</i>		
Tracheostomy	1	0
<i>Uterine therapeutic procedures</i>		
Endometrial ablation	3	0
<i>Vascular therapeutic procedures NEC</i>		
Angioplasty	1	0
Surgical & medical procedures SOC TOTAL	452	1

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Hypertensive crisis	10	0
Hypertensive urgency	1	0
Malignant hypertension	4	0
<i>Aneurysms and dissections non-site specific</i>		
Aneurysm	2	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>Aortic necrosis and vascular insufficiency</i>		
Aortic occlusion	1	0
<i>Arterial infections and inflammations</i>		
Arteritis	1	0
Giant cell arteritis	12	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	65	0
Hypoperfusion	2	0
Hypovolaemic shock	1	1
Neurogenic shock	21	0
Peripheral circulatory failure	6	0
Shock	19	0
<i>Haemorrhages NEC</i>		
Arterial haemorrhage	1	0
Bloody discharge	22	0
Haematoma	44	0
Haemorrhage	1125	2
Internal haemorrhage	8	0
Venous haemorrhage	2	0
<i>Lymphangiopathies</i>		
Lymphangiopathy	1	0
Lymphocele	4	0
<i>Lymphoedemas</i>		
Lymphoedema	188	0
<i>Non-site specific embolism and thrombosis</i>		
Arterial thrombosis	4	0
Embolism	60	0
Embolism venous	6	0
Microembolism	1	0
Thrombosis	388	8
Venous thrombosis	7	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arterial occlusive disease	2	0

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Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
Arterial spasm	1	0
Arteriosclerosis	2	0
Haemorrhagic infarction	1	0
Infarction	4	0
Ischaemia	10	0
Peripheral venous disease	1	0
Vascular occlusion	1	0
Vasospasm	1	0
<i>Non-site specific vascular disorders NEC</i>		
Capillary disorder	1	0
Capillary fragility	1	0
Superficial vein prominence	1	0
Vascular pain	31	0
Vascular wall hypertrophy	1	0
Vasodilatation	35	0
Vein discolouration	5	0
Vein disorder	6	0
Vein rupture	5	0
<i>Peripheral embolism and thrombosis</i>		
Axillary vein thrombosis	1	0
Blue toe syndrome	25	0
Deep vein thrombosis	258	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 artery embolism	1	0
Subclavian vein thrombosis	3	0
Superficial vein thrombosis	17	0
Thrombophlebitis	22	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	41	0
Erythromelalgia	2	0
Flushing	393	0
Hot flush	1069	0
Peripheral vascular disorder	1	0
Vein wall hypertrophy	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Claudication of jaw muscles	1	0
Extremity necrosis	3	0
Iliac artery occlusion	1	0
Intermittent claudication	3	0
Ischaemic limb pain	1	0
Jugular vein occlusion	2	0
Peripheral arterial occlusive disease	2	0
Peripheral artery occlusion	1	0
Peripheral coldness	295	0
Peripheral ischaemia	12	0
Poor peripheral circulation	16	0
Raynaud's phenomenon	53	0
Subclavian vein occlusion	1	0
Vasoconstriction	2	0

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Vascular disorders Vascular disorders cont'd		
<i>Phlebitis NEC</i>		
Phlebitis	31	0
Phlebitis superficial	6	0
<i>Site specific vascular disorders NEC</i>		
Aortic dilatation	1	0
Inferior vena cava dilatation	1	0
Pallor	348	0
<i>Varicose veins NEC</i>		
Spider vein	6	0
Varicophlebitis	4	0
Varicose vein	30	0
<i>Vascular hypertensive disorders NEC</i>		
Diastolic hypertension	3	0
Essential hypertension	3	0
Hypertension	528	1
Labile hypertension	1	0
Orthostatic hypertension	1	0
Secondary hypertension	1	0
Systolic hypertension	6	0
White coat hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Diastolic hypotension	1	0
Hypotension	372	1
Orthostatic hypotension	30	0
<i>Vasculitides NEC</i>		
Behcet's syndrome	4	0
Diffuse vasculitis	1	0
Granulomatosis with polyangiitis	2	0
MAGIC syndrome	1	0
Thromboangiitis obliterans	1	0
Vasculitis	45	0
<i>Vena caval embolism and thrombosis</i>		
Vena cava embolism	1	0
Vena cava thrombosis	1	0
Vascular disorders SOC TOTAL	5811	15
TOTAL REACTIONS FOR DRUG	363704	597
TOTAL REPORTS	128734	
TOTAL FATAL OUTCOME REPORTS		597