

## COVID-19 Pfizer / BioNTech Vaccine Analysis Print

All UK spontaneous reports received between 09/12/20 and 08/12/21 for Pfizer / BioNTech vaccine.

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: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<b><i>Anaemia deficiencies</i></b>		
Anaemia folate deficiency	1	0
Anaemia vitamin B12 deficiency	3	0
Deficiency anaemia	1	0
Iron deficiency anaemia	8	0
<b><i>Anaemias NEC</i></b>		
Anaemia	119	0
Anaemia macrocytic	2	0
Anaemia megaloblastic	1	0
Autoimmune anaemia	3	0
Blood loss anaemia	1	0
Microcytic anaemia	1	0
<b><i>Anaemias haemolytic NEC</i></b>		
Coombs negative haemolytic anaemia	1	0
Haemolytic anaemia	7	0
<b><i>Anaemias haemolytic immune</i></b>		
Autoimmune haemolytic anaemia	16	0
Cold type haemolytic anaemia	1	0
Evans syndrome	1	0
Warm type haemolytic anaemia	1	0
<b><i>Anaemias haemolytic mechanical factor</i></b>		
Microangiopathic haemolytic anaemia	1	0
<b><i>Bleeding tendencies</i></b>		
Haemorrhagic diathesis	1	0
Increased tendency to bruise	47	0
Spontaneous haematoma	2	0
<b><i>Coagulation factor deficiencies</i></b>		
Acquired haemophilia	2	0
<b><i>Coagulopathies</i></b>		
Abnormal clotting factor	4	0
Antiphospholipid syndrome	6	0
Coagulopathy	24	1
Disseminated intravascular coagulation	2	0
Hypercoagulation	3	0
Thrombotic microangiopathy	2	0
<b><i>Eosinophilic disorders</i></b>		
Eosinophilia	12	0
<b><i>Haematological disorders</i></b>		
Blood disorder	4	0
Hypergammaglobulinaemia	1	0
Hyperviscosity syndrome	1	0
Mast cell activation syndrome	7	0
Methaemoglobinaemia	1	0
<b><i>Haemolyses NEC</i></b>		
Haemolysis	6	0
Intravascular haemolysis	1	0
Jaundice acholuric	1	0
<b><i>Leukocytoses NEC</i></b>		
Leukocytosis	2	0
Lymphocytosis	6	0
Neutrophilia	11	0
<b><i>Leukopenias NEC</i></b>		
Leukopenia	4	1

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Reaction Name	Total	Fatal
<b>Blood disorders</b> Blood disorders cont'd		
Lymphopenia	4	0
<b><i>Lymphatic system disorders NEC</i></b>		
Abdominal lymphadenopathy	3	0
Hilar lymphadenopathy	2	0
Lymph node pain	1812	0
Lymph node ulcer	1	0
Lymphadenitis	149	0
Lymphadenopathy	11194	0
Lymphatic disorder	2	0
Lymphatic insufficiency	1	0
Necrotic lymphadenopathy	3	0
Pseudolymphoma	11	0
Retroperitoneal lymphadenopathy	1	0
<b><i>Marrow depression and hypoplastic anaemias</i></b>		
Aplasia pure red cell	2	0
Aplastic anaemia	1	1
Hypoplastic anaemia	2	0
Myelosuppression	1	0
Pancytopenia	8	0
<b><i>Neutropenias</i></b>		
Autoimmune neutropenia	2	0
Neutropenia	39	0
<b><i>Platelet disorders NEC</i></b>		
Platelet anisocytosis	1	0
Platelet disorder	3	0
<b><i>Polycythaemia (excl rubra vera)</i></b>		
Polycythaemia	3	0
<b><i>Purpuras (excl thrombocytopenic)</i></b>		
Purpura non-thrombocytopenic	1	0
<b><i>Red blood cell abnormal findings NEC</i></b>		
Macrocytosis	1	0
Polychromasia	2	0
Red blood cell abnormality	2	0
<b><i>Spleen disorders</i></b>		
Spleen atrophy	1	0
Splenic infarction	3	0
Splenic thrombosis	1	0
Splenic vein thrombosis	2	0
Splenomegaly	11	0
<b><i>Thrombocytopenias</i></b>		
Acquired amegakaryocytic thrombocytopenia	1	0
Immune thrombocytopenia	78	0
Thrombocytopenia	221	1
Thrombocytopenic purpura	8	0
Thrombotic thrombocytopenic purpura	6	0
<b><i>Thrombocytoses</i></b>		
Thrombocytosis	6	0
<b>Blood disorders SOC TOTAL</b>	<b>13907</b>	<b>4</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i><b>Aortic valvular disorders</b></i>		
Aortic valve incompetence	1	0
<i><b>Cardiac conduction disorders</b></i>		
Atrioventricular block	22	1
Atrioventricular block complete	3	1
Atrioventricular block first degree	1	0
Atrioventricular block second degree	3	0
Bundle branch block	2	0
Bundle branch block left	3	0
Bundle branch block right	2	0
<i><b>Cardiac disorders NEC</b></i>		
Acute cardiac event	5	0
Cardiac disorder	64	1
Cardiac dysfunction	1	0
Cardiovascular deconditioning	1	0
Cardiovascular disorder	6	0
Intracardiac thrombus	6	0
<i><b>Cardiac hypertensive complications</b></i>		
Hypertensive heart disease	2	1
<i><b>Cardiac infections and inflammations NEC</b></i>		
Carditis	4	0
<i><b>Cardiac neoplasms NEC</b></i>		
Pericardial cyst	1	0
<i><b>Cardiac signs and symptoms NEC</b></i>		
Cardiac discomfort	27	0
Cardiovascular symptom	1	0
Palpitations	4093	1
<i><b>Cardiac valve disorders NEC</b></i>		
Cardiac valve disease	2	0
Heart valve incompetence	3	0
<i><b>Cardiomyopathies</b></i>		
Cardiomyopathy	11	0
Congestive cardiomyopathy	6	0
Stress cardiomyopathy	2	0
<i><b>Coronary artery disorders NEC</b></i>		
Arteriosclerosis coronary artery	1	0
Coronary artery disease	6	3
Coronary artery occlusion	2	0
Coronary artery thrombosis	2	1
<i><b>Endocarditis NEC</b></i>		
Endocarditis noninfective	1	1
<i><b>Heart failures NEC</b></i>		
Cardiac failure	72	9
Cardiac failure acute	5	1
Cardiac failure chronic	2	0
Cardiac failure congestive	4	1
Cardiogenic shock	4	1
Cardiopulmonary failure	1	1
<i><b>Ischaemic coronary artery disorders</b></i>		
Acute coronary syndrome	7	1
Acute myocardial infarction	23	1
Angina pectoris	238	1
Angina unstable	3	0

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<b>Cardiac disorders</b> Cardiac disorders cont'd		
Arteriospasm coronary	3	0
Microvascular coronary artery disease	2	0
Myocardial infarction	235	37
Myocardial ischaemia	10	5
<b>Left ventricular failures</b>		
Acute left ventricular failure	1	1
Left ventricular failure	7	2
<b>Mitral valvular disorders</b>		
Mitral valve incompetence	6	0
Mitral valve prolapse	1	0
<b>Myocardial disorders NEC</b>		
Cardiac amyloidosis	1	0
Cardiac aneurysm	1	1
Cardiomegaly	34	2
Left atrial dilatation	1	0
Left ventricular dysfunction	11	0
Left ventricular enlargement	2	0
Left ventricular hypertrophy	2	0
Myocardial fibrosis	5	0
Myocardial haemorrhage	1	0
Myocardial injury	12	0
Myocardial necrosis	1	0
Myocardial oedema	5	0
Myocardial rupture	1	0
Right atrial enlargement	1	0
Right ventricular enlargement	1	0
Ventricular dysfunction	2	0
Ventricular hypertrophy	1	0
Ventricular hypokinesia	1	0
<b>Noninfectious myocarditis</b>		
Eosinophilic myocarditis	1	0
Hypersensitivity myocarditis	1	0
Myocarditis	507	1
<b>Noninfectious pericarditis</b>		
Pericarditis	365	1
Pericarditis constrictive	1	0
<b>Pericardial disorders NEC</b>		
Cardiac tamponade	1	1
Pericardial effusion	38	1
Pericardial fibrosis	1	0
Pericardial haemorrhage	4	3
Pericardial rub	2	0
<b>Rate and rhythm disorders NEC</b>		
Arrhythmia	141	0
Bradycardia	62	0
Bradycardia foetal	2	1
Cardiac flutter	452	0
Extrasystoles	170	0
Heart alternation	1	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	21	0
Tachyarrhythmia	6	0
Tachycardia	1272	0

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<b>Cardiac disorders</b> Cardiac disorders cont'd		
Tachycardia foetal	1	0
Tachycardia paroxysmal	1	0
<b>Right ventricular failures</b>		
Cor pulmonale	1	0
Right ventricular failure	1	0
<b>Supraventricular arrhythmias</b>		
Arrhythmia supraventricular	12	0
Atrial fibrillation	224	0
Atrial flutter	32	0
Atrial tachycardia	10	0
Nodal arrhythmia	1	0
Sinus arrest	1	0
Sinus arrhythmia	6	0
Sinus bradycardia	13	0
Sinus node dysfunction	1	0
Sinus tachycardia	60	0
Supraventricular extrasystoles	4	0
Supraventricular tachycardia	39	0
<b>Tricuspid valvular disorders</b>		
Tricuspid valve incompetence	5	0
<b>Ventricular arrhythmias and cardiac arrest</b>		
Cardiac arrest	109	40
Cardio-respiratory arrest	1	1
Pulseless electrical activity	4	0
Ventricular arrhythmia	5	0
Ventricular extrasystoles	25	0
Ventricular fibrillation	8	1
Ventricular tachycardia	13	0
<b>Cardiac disorders SOC TOTAL</b>	<b>8617</b>	<b>124</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i><b>Autosomal chromosomal abnormalities</b></i>		
Trisomy 8	1	0
<i><b>Cardiac disorders congenital NEC</b></i>		
Heart disease congenital	13	0
<i><b>Cardiac hypoplasias congenital</b></i>		
Ventricular hypoplasia	1	0
<i><b>Cardiac septal defects congenital</b></i>		
Atrial septal defect	2	0
Hypertrophic cardiomyopathy	1	0
Ventricular septal defect	1	0
<i><b>Cardiac valve disorders congenital</b></i>		
Bicuspid aortic valve	1	0
<i><b>Central nervous system disorders congenital NEC</b></i>		
Spina bifida	2	1
Syringomyelia	1	0
<i><b>Cerebellar disorders congenital</b></i>		
Arnold-Chiari malformation	1	0
Hereditary ataxia	1	0
<i><b>Cerebral disorders congenital</b></i>		
Anencephaly	2	0
Cerebral palsy	3	0
<i><b>Coagulation disorders congenital</b></i>		
Haemophilia	2	0
<i><b>Congenital disorders NEC</b></i>		
Foetal malformation	1	0
Heterotaxia	1	0
<i><b>Connective tissue disorders congenital</b></i>		
Ehlers-Danlos syndrome	2	0
<i><b>Gastrointestinal tract disorders congenital NEC</b></i>		
Gastroschisis	2	0
<i><b>Great vessel disorders congenital</b></i>		
Congenital great vessel anomaly	1	0
Transposition of the great vessels	1	0
<i><b>Haematological disorders congenital NEC</b></i>		
Amegakaryocytic thrombocytopenia	1	0
Neonatal alloimmune thrombocytopenia	1	0
<i><b>Haemoglobinopathies congenital</b></i>		
Congenital methaemoglobinaemia	1	0
<i><b>Inborn errors of lipid metabolism</b></i>		
Short-chain acyl-coenzyme A dehydrogenase deficiency	1	0
<i><b>Inborn errors of metabolism NEC</b></i>		
Alpha-1 antitrypsin deficiency	1	0
<i><b>Inborn errors of porphyrin metabolism</b></i>		
Porphyria	1	0
<i><b>Laryngeal and tracheal disorders congenital</b></i>		
Laryngomalacia	1	0
<i><b>Lymphatic system disorders congenital</b></i>		
Cystic lymphangioma	3	0
<i><b>Male reproductive tract disorders congenital</b></i>		
Cryptorchism	1	0
Micropenis	3	0
Phimosis	1	0
<i><b>Musculoskeletal and connective tissue disorders of limbs congenital</b></i>		

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Reaction Name	Total	Fatal
<b>Congenital disorders</b> Congenital disorders cont'd		
Developmental hip dysplasia	1	0
<b>Musculoskeletal and connective tissue disorders of skull congenital</b>		
Platybasia	1	0
<b>Musculoskeletal and connective tissue disorders of spine congenital</b>		
Block vertebra	1	0
Brachyolmia	1	0
<b>Neurological disorders congenital NEC</b>		
Familial hemiplegic migraine	2	0
Familial periodic paralysis	1	0
Moebius II syndrome	1	0
Tourette's disorder	2	0
<b>Ocular disorders congenital NEC</b>		
Colour blindness	4	0
Congenital eye disorder	1	0
<b>Palate disorders congenital</b>		
Cleft lip and palate	2	0
<b>Peripheral nervous system disorders congenital NEC</b>		
Hereditary neuropathy with liability to pressure palsies	1	0
Paroxysmal extreme pain disorder	1	0
<b>Pulmonary and bronchial disorders congenital</b>		
Congenital cystic lung	1	0
<b>Retinal disorders congenital</b>		
Retinitis pigmentosa	1	0
<b>Sex chromosomal abnormalities</b>		
Turner's syndrome	1	0
<b>Skin and subcutaneous tissue disorders congenital NEC</b>		
Acral peeling skin syndrome	1	0
<b>Tongue disorders congenital</b>		
Ankyloglossia congenital	1	0
<b>Vascular anomalies congenital NEC</b>		
Congenital LUMBAR syndrome	1	0
<b>Venous disorders congenital</b>		
Anomalous pulmonary venous connection	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>81</b>	<b>1</b>



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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i><b>Ear disorders NEC</b></i>		
Ear canal erythema	1	0
Ear congestion	32	0
Ear discomfort	95	0
Ear disorder	17	0
Ear haemorrhage	12	0
Ear pain	971	0
Ear pruritus	9	0
Ear swelling	35	0
Otorrhoea	5	0
Paraesthesia ear	1	0
<i><b>Eustachian tube disorders</b></i>		
Eustachian tube disorder	4	0
Eustachian tube dysfunction	9	0
Eustachian tube obstruction	4	0
<i><b>External ear disorders NEC</b></i>		
Auricular swelling	2	0
Excessive cerumen production	10	0
External ear pain	4	0
Red ear syndrome	2	0
<i><b>External ear infections and inflammations</b></i>		
External ear inflammation	2	0
<i><b>Hearing disorders NEC</b></i>		
Auditory disorder	6	0
Diplacusis	2	0
<i><b>Hearing losses</b></i>		
Conductive deafness	1	0
Deafness	243	0
Deafness bilateral	9	0
Deafness neurosensory	18	0
Deafness transitory	9	0
Deafness unilateral	33	0
Hypoacusis	187	0
Sudden hearing loss	47	0
<i><b>Hyperacusia</b></i>		
Hyperacusis	60	0
Misophonia	3	0
<i><b>Inner ear disorders NEC</b></i>		
Acute vestibular syndrome	2	0
Inner ear disorder	13	0
Meniere's disease	11	0
Vestibular disorder	11	0
<i><b>Inner ear infections and inflammations</b></i>		
Inner ear inflammation	10	0
<i><b>Inner ear signs and symptoms</b></i>		
Motion sickness	62	0
Tinnitus	2011	0
Vertigo	1410	0
Vertigo labyrinthine	11	0
Vertigo positional	75	0
<i><b>Mastoid disorders</b></i>		
Mastoid effusion	1	0
<i><b>Middle ear disorders NEC</b></i>		

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Reaction Name	Total	Fatal
<b>Ear disorders</b> Ear disorders cont'd		
Middle ear disorder	3	0
Middle ear effusion	1	0
<b><i>Middle ear infections and inflammations</i></b>		
Middle ear inflammation	1	0
<b><i>Tympanic membrane disorders (excl infections)</i></b>		
Tympanic membrane perforation	3	0
<b>Ear disorders SOC TOTAL</b>	<b>5458</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<i><b>Acute and chronic thyroiditis</b></i>		
Autoimmune thyroiditis	2	0
Thyroiditis	21	0
Thyroiditis acute	3	0
Thyroiditis subacute	3	0
<i><b>Adrenal cortical hypofunctions</b></i>		
Addison's disease	2	0
Adrenal insufficiency	3	0
Adrenocortical insufficiency acute	15	0
<i><b>Adrenal gland disorders NEC</b></i>		
Adrenal haemorrhage	3	0
<i><b>Anterior pituitary hyperfunction</b></i>		
Pituitary-dependent Cushing's syndrome	1	0
<i><b>Anterior pituitary hypofunction</b></i>		
Hypopituitarism	1	0
<i><b>Endocrine abnormalities of gonadal function NEC</b></i>		
Oestrogen deficiency	1	0
<i><b>Endocrine abnormalities of puberty</b></i>		
Delayed menarche	4	0
Premature menarche	19	0
<i><b>Female gonadal function disorders</b></i>		
Anovulatory cycle	47	0
Ovulation delayed	32	0
<i><b>Male gonadal function disorders</b></i>		
Androgen deficiency	1	0
<i><b>Thyroid disorders NEC</b></i>		
Autoimmune thyroid disorder	1	0
Goitre	13	0
Thyroid disorder	8	0
Thyroid mass	1	0
Thyroid pain	10	0
<i><b>Thyroid hyperfunction disorders</b></i>		
Basedow's disease	11	0
Hyperthyroidism	41	0
Thyrotoxic crisis	3	0
<i><b>Thyroid hypofunction disorders</b></i>		
Autoimmune hypothyroidism	1	0
Hypothyroidism	30	0
Immune-mediated hypothyroidism	1	0
Myxoedema	1	0
<b>Endocrine disorders SOC TOTAL</b>	<b>279</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<b><i>Amblyopic vision impairment</i></b>		
Amblyopia	7	0
<b><i>Anterior chamber bleeding and vascular disorders</i></b>		
Spontaneous hyphaema	1	0
<b><i>Cataract conditions</i></b>		
Cataract	12	0
<b><i>Choroid and vitreous haemorrhages and vascular disorders</i></b>		
Choroidal haemorrhage	1	0
Choroidal neovascularisation	1	0
Vitreous haemorrhage	4	0
<b><i>Choroid and vitreous structural change, deposit and degeneration</i></b>		
Chorioretinopathy	6	0
Vitreous detachment	17	0
Vitreous floaters	96	0
<b><i>Colour blindness (incl acquired)</i></b>		
Dyschromatopsia	9	0
<b><i>Conjunctival and corneal bleeding and vascular disorders</i></b>		
Conjunctival haemorrhage	45	0
Scleral haemorrhage	1	0
<b><i>Conjunctival infections, irritations and inflammations</i></b>		
Conjunctival hyperaemia	2	0
Conjunctival irritation	1	0
Conjunctival oedema	3	0
Conjunctivitis allergic	1	0
<b><i>Corneal infections, oedemas and inflammations</i></b>		
Corneal oedema	2	0
Keratitis	6	0
Ulcerative keratitis	5	0
<b><i>Corneal structural change, deposit and degeneration</i></b>		
Corneal scar	1	0
<b><i>Eyelid movement disorders</i></b>		
Blepharospasm	141	0
Excessive eye blinking	6	0
Eyelid function disorder	3	0
Eyelid myokymia	4	0
Eyelid ptosis	45	0
Paralytic lagophthalmos	2	0
<b><i>Glaucomas (excl congenital)</i></b>		
Angle closure glaucoma	2	0
Glaucoma	6	0
Ocular hypertension	1	0
<b><i>Iris and ciliary body structural change, deposit and degeneration</i></b>		
Eye colour change	3	0
<b><i>Iris and uveal tract infections, irritations and inflammations</i></b>		
Autoimmune uveitis	2	0
Iridocyclitis	15	0
Iritis	10	0
Uveitis	48	0
<b><i>Lacrimation disorders</i></b>		
Dry eye	152	0
Lacrimation increased	135	0
<b><i>Lid bleeding and vascular disorders</i></b>		
Eyelid bleeding	1	0

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<b>Eye disorders</b> Eye disorders cont'd		
<b><i>Lid, lash and lacrimal infections, irritations and inflammations</i></b>		
Blepharitis	15	0
Chalazion	7	0
Eczema eyelids	8	0
Erythema of eyelid	9	0
Eyelid cyst	5	0
Eyelid irritation	3	0
Eyelid margin crusting	4	0
Eyelid oedema	6	0
Eyelid rash	16	0
Meibomian gland dysfunction	1	0
Swelling of eyelid	122	0
Swollen tear duct	2	0
<b><i>Lid, lash and lacrimal structural disorders</i></b>		
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
<b><i>Ocular bleeding and vascular disorders NEC</i></b>		
Eye haematoma	4	0
Eye haemorrhage	29	0
Ocular vascular disorder	2	0
Ophthalmic vein thrombosis	1	0
<b><i>Ocular disorders NEC</i></b>		
Dark circles under eyes	8	0
Eye disorder	34	0
Eye oedema	18	0
Eye pain	1101	0
Eye swelling	521	0
Eye symptom	9	0
Eye ulcer	4	0
Eyelid disorder	14	0
Eyelid pain	12	0
Eyelids pruritus	6	0
Ocular discomfort	26	0
Periorbital oedema	18	0
Periorbital pain	1	0
Periorbital swelling	118	0
Retinal disorder	2	0
Vitreous disorder	1	0
<b><i>Ocular infections, inflammations and associated manifestations</i></b>		
Eye allergy	16	0
Eye discharge	29	0
Eye inflammation	29	0
Eye irritation	93	0
Eye pruritus	239	0
Limbal swelling	4	0
Ocular hyperaemia	225	0

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<b>Eye disorders</b> Eye disorders cont'd		
<b><i>Ocular nerve and muscle disorders</i></b>		
Binocular eye movement disorder	1	0
Extraocular muscle disorder	1	0
Extraocular muscle paresis	2	0
Eye movement disorder	36	0
Gaze palsy	1	0
Ocular myasthenia	1	0
Ophthalmoplegia	5	0
Strabismus	8	0
<b><i>Ocular sensation disorders</i></b>		
Abnormal sensation in eye	20	0
Asthenopia	153	0
Eye paraesthesia	2	0
Eyelid sensory disorder	2	0
Foreign body sensation in eyes	16	0
Hypoaesthesia eye	15	0
Photophobia	478	0
<b><i>Optic disc abnormalities NEC</i></b>		
Papilloedema	6	0
<b><i>Optic nerve bleeding and vascular disorders</i></b>		
Optic disc haemorrhage	1	0
Optic ischaemic neuropathy	2	0
<b><i>Orbital infections, inflammations and irritations</i></b>		
Parophthalmia	1	0
<b><i>Orbital structural change, deposit and degeneration</i></b>		
Orbital oedema	2	0
<b><i>Pupil disorders</i></b>		
Miosis	2	0
Mydriasis	22	0
Pupil fixed	2	0
Pupillary disorder	1	0
Pupils unequal	12	0
<b><i>Refractive and accommodative disorders</i></b>		
Accommodation disorder	1	0
Altered visual depth perception	3	0
Astigmatism	2	0
Hypermetropia	2	0
Myopia	1	0
<b><i>Retinal bleeding and vascular disorders (excl retinopathy)</i></b>		
Retinal artery occlusion	14	0
Retinal artery thrombosis	2	0
Retinal haemorrhage	7	0
Retinal vascular thrombosis	1	0
Retinal vein occlusion	36	0
Retinal vein thrombosis	2	0
<b><i>Retinal structural change, deposit and degeneration</i></b>		
Macular degeneration	4	0
Macular hole	3	0
Macular rupture	1	0
Maculopathy	1	0
Neovascular age-related macular degeneration	4	0
Retinal degeneration	1	0
Retinal detachment	6	0

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Eye disorders</b> Eye disorders cont'd		
Retinal tear	2	0
Retinal toxicity	3	0
<b><i>Retinal, choroid and vitreous infections and inflammations</i></b>		
Birdshot chorioretinopathy	2	0
Cystoid macular oedema	1	0
Macular oedema	5	0
Retinal vasculitis	3	0
<b><i>Retinopathies NEC</i></b>		
Acute macular neuroretinopathy	2	0
Retinal exudates	2	0
Retinopathy	4	0
<b><i>Scleral infections, irritations and inflammations</i></b>		
Episcleritis	7	0
Scleritis	5	0
<b><i>Scleral structural change, deposit and degeneration</i></b>		
Scleral discolouration	2	0
<b><i>Structural change, deposit and degeneration of eye NEC</i></b>		
Endocrine ophthalmopathy	1	0
Exophthalmos	1	0
<b><i>Visual colour distortions</i></b>		
Chloropsia	2	0
Chromatopsia	1	0
Cyanopsia	3	0
Erythropsia	2	0
Xanthopsia	1	0
<b><i>Visual disorders NEC</i></b>		
Charles Bonnet syndrome	2	0
Diplopia	160	0
Dysmetropsia	1	0
Glare	1	0
Halo vision	7	0
Heteronymous diplopia	1	0
Metamorphopsia	21	0
Oscillopsia	3	0
Photopsia	133	0
Scintillating scotoma	4	0
Vision blurred	1218	0
Visual brightness	3	0
Visual snow syndrome	8	0
<b><i>Visual field disorders</i></b>		
Visual field defect	32	0
<b><i>Visual impairment and blindness (excl colour blindness)</i></b>		
Amaurosis fugax	3	0
Blindness	132	0
Blindness cortical	1	0
Blindness transient	15	0
Blindness unilateral	15	0
Central vision loss	6	0
Sudden visual loss	3	0
Visual acuity reduced	25	0
Visual acuity reduced transiently	1	0
Visual impairment	379	0
<b><i>Visual pathway disorders</i></b>		

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Eye disorders</b> Eye disorders cont'd		
Optic nerve disorder	1	0
<b>Eye disorders SOC TOTAL</b>	<b>6682</b>	<b>0</b>



## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<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	15	0
Pancreatitis acute	15	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	14	0
<i>Anal and rectal signs and symptoms</i>		
Anal erythema	1	0
Anal hypoaesthesia	1	0
Anal pruritus	1	0
Anal spasm	1	0
Anorectal discomfort	4	0
Anorectal swelling	1	0
Rectal discharge	2	0
Rectal tenesmus	1	0
<i>Anal and rectal ulcers and perforation</i>		
Anal ulcer	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	47	1
Colitis ischaemic	1	0
Colitis microscopic	2	0
Colitis ulcerative	70	0
Crohn's disease	39	0
Eosinophilic colitis	1	0
Inflammatory bowel disease	8	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	3	0
Teething	8	0
Tooth disorder	2	0
Tooth socket haemorrhage	1	0
<i>Dental pain and sensation disorders</i>		

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Dental discomfort	6	0
Dental paraesthesia	13	0
Hyperaesthesia teeth	36	0
Toothache	164	0
<b><i>Dental surface disorders</i></b>		
Tooth discolouration	9	0
<b><i>Diaphragmatic hernias</i></b>		
Hiatus hernia	8	0
<b><i>Diarrhoea (excl infective)</i></b>		
Diarrhoea	5390	0
Diarrhoea haemorrhagic	22	0
<b><i>Diverticula</i></b>		
Diverticulum	5	0
Diverticulum intestinal	1	0
<b><i>Duodenal and small intestinal stenosis and obstruction</i></b>		
Small intestinal obstruction	2	0
<b><i>Duodenal ulcers and perforation</i></b>		
Duodenal ulcer haemorrhage	1	0
Duodenal ulcer perforation	3	0
<b><i>Dyspeptic signs and symptoms</i></b>		
Dyspepsia	444	0
Epigastric discomfort	14	0
Eructation	51	0
<b><i>Faecal abnormalities NEC</i></b>		
Abnormal faeces	19	0
Faecaloma	4	0
Faeces discoloured	59	0
Faeces hard	2	0
Faeces pale	4	0
Faeces soft	12	0
Mucous stools	10	0
<b><i>Flatulence, bloating and distension</i></b>		
Abdominal distension	513	0
Aerophagia	3	0
Flatulence	179	0
<b><i>Gastric and oesophageal haemorrhages</i></b>		
Gastric haemorrhage	5	1
Mallory-Weiss syndrome	1	0
Oesophageal varices haemorrhage	1	0
<b><i>Gastric ulcers and perforation</i></b>		
Gastric ulcer	6	0
<b><i>Gastritis (excl infective)</i></b>		
Chronic gastritis	3	0
Gastritis	58	0
Reflux gastritis	6	0
<b><i>Gastrointestinal and abdominal pains (excl oral and throat)</i></b>		
Abdominal migraine	2	0
Abdominal pain	1441	0
Abdominal pain lower	131	0
Abdominal pain upper	2391	0
Abdominal rigidity	24	0
Abdominal tenderness	13	0
Gastrointestinal pain	135	0

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Oesophageal pain	13	0
<b><i>Gastrointestinal atonic and hypomotility disorders NEC</i></b>		
Constipation	250	0
Duodenogastric reflux	4	0
Gastric dilatation	7	0
Gastrooesophageal reflux disease	152	0
Impaired gastric emptying	9	0
Infrequent bowel movements	3	0
Intestinal dilatation	1	0
Intestinal pseudo-obstruction	2	0
<b><i>Gastrointestinal disorders NEC</i></b>		
Appendix disorder	1	0
Food poisoning	7	0
Functional gastrointestinal disorder	10	0
Gastric disorder	10	0
Gastrointestinal disorder	23	0
Stomach mass	4	0
<b><i>Gastrointestinal dyskinetic disorders</i></b>		
Bowel movement irregularity	6	0
Change of bowel habit	6	0
Dyschezia	3	0
Gastrointestinal motility disorder	3	0
Oesophageal achalasia	1	0
<b><i>Gastrointestinal fistulae</i></b>		
Diverticular fistula	2	0
<b><i>Gastrointestinal inflammatory disorders NEC</i></b>		
Duodenitis	1	0
Enteritis	6	0
Epiploic appendagitis	2	0
Gastrointestinal inflammation	3	0
Gastrointestinal tract irritation	1	0
Intestinal angioedema	2	0
<b><i>Gastrointestinal mucosal dystrophies and secretion disorders</i></b>		
Barrett's oesophagus	1	0
Hyperchlorhydria	4	0
<b><i>Gastrointestinal signs and symptoms NEC</i></b>		
Abdominal discomfort	613	0
Abdominal symptom	1	0
Acute abdomen	6	0
Anal incontinence	19	0
Breath odour	19	0
Dysphagia	206	1
Gastrointestinal wall thickening	1	0
Odynophagia	37	0
<b><i>Gastrointestinal spastic and hypermotility disorders</i></b>		
Cardiospasm	1	0
Defaecation urgency	11	0
Frequent bowel movements	28	0
Gastrointestinal hypermotility	1	0
Irritable bowel syndrome	84	0
Oesophageal spasm	4	0
Pylorospasm	1	0
<b><i>Gastrointestinal stenosis and obstruction NEC</i></b>		

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Intestinal obstruction	4	0
Neonatal intestinal obstruction	1	0
<b><i>Gastrointestinal vascular malformations</i></b>		
Gastric antral vascular ectasia	11	0
<b><i>Gastrointestinal vascular occlusion and infarction</i></b>		
Intestinal ischaemia	7	2
Mesenteric vein thrombosis	7	0
Omental infarction	1	0
Thrombosis mesenteric vessel	2	0
Visceral venous thrombosis	1	0
<b><i>Gingival disorders, signs and symptoms NEC</i></b>		
Gingival blister	13	0
Gingival discomfort	8	0
Gingival disorder	4	0
Gingival erythema	2	0
Gingival hypertrophy	1	0
Gingival oedema	1	0
Gingival pain	109	0
Gingival pruritus	1	0
Gingival recession	1	0
Gingival swelling	35	0
Gingival ulceration	2	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	8	0
<b><i>Gingival haemorrhages</i></b>		
Gingival bleeding	65	0
<b><i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i></b>		
Gastric varices	1	0
Haemorrhoidal haemorrhage	1	0
Haemorrhoids	31	1
Haemorrhoids thrombosed	1	0
<b><i>Inguinal hernias</i></b>		
Inguinal hernia	1	0
<b><i>Intestinal haemorrhages</i></b>		
Anal haemorrhage	20	1
Intestinal haemorrhage	1	0
Rectal haemorrhage	70	0
Small intestinal haemorrhage	5	0
<b><i>Intestinal ulcers and perforation NEC</i></b>		
Intestinal perforation	5	2
Large intestinal ulcer	1	0
Large intestine perforation	1	0
<b><i>Large intestinal stenosis and obstruction</i></b>		
Large intestinal obstruction	1	1
<b><i>Malabsorption syndromes</i></b>		
Bile acid malabsorption	2	0
Coeliac disease	12	0
Malabsorption	1	0
Steatorrhoea	4	0
<b><i>Nausea and vomiting symptoms</i></b>		
Discoloured vomit	12	0
Infantile vomiting	7	0
Nausea	13591	0

## Case Series Drug Analysis Print

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Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Regurgitation	1	0
Retching	104	0
Vomiting	4426	1
Vomiting projectile	62	0
<b><i>Non-mechanical ileus</i></b>		
Ileus paralytic	2	0
<b><i>Non-site specific gastrointestinal haemorrhages</i></b>		
Gastrointestinal haemorrhage	16	1
Haematemesis	32	2
Haematochezia	51	0
Melaena	9	0
Upper gastrointestinal haemorrhage	11	0
<b><i>Oesophageal stenosis and obstruction</i></b>		
Oesophageal stenosis	3	0
<b><i>Oesophagitis (excl infective)</i></b>		
Eosinophilic oesophagitis	1	0
Oesophagitis	4	0
<b><i>Oral dryness and saliva altered</i></b>		
Aptyalism	3	0
Dry mouth	489	0
Lip dry	39	0
Saliva altered	7	0
Salivary hypersecretion	49	0
<b><i>Oral soft tissue disorders NEC</i></b>		
Angina bullosa haemorrhagica	1	0
Chapped lips	22	0
Cheilitis	25	0
Enlarged uvula	14	0
Leukoplakia oral	2	0
Lip blister	30	0
Lip disorder	5	0
Oral disorder	20	0
Oral lichen planus	12	0
Oral mucosal hypertrophy	1	0
Oral papule	1	0
Uvulitis	5	0
<b><i>Oral soft tissue haemorrhages</i></b>		
Lip haemorrhage	1	0
Mouth haemorrhage	16	0
Oral blood blister	14	0
Oral purpura	2	0
<b><i>Oral soft tissue infections</i></b>		
Angular cheilitis	4	0
<b><i>Oral soft tissue signs and symptoms</i></b>		
Anaesthesia oral	3	0
Burning mouth syndrome	6	0
Coating in mouth	1	0
Hypoaesthesia oral	468	0
Lip discolouration	7	0
Lip erythema	4	0
Lip exfoliation	5	0
Lip pain	52	0
Lip pruritus	15	0

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Lip scab	1	0
Oral discomfort	82	0
Oral dysaesthesia	1	0
Oral mucosal blistering	16	0
Oral mucosal discolouration	1	0
Oral mucosal eruption	17	0
Oral mucosal erythema	7	0
Oral mucosal exfoliation	9	0
Oral mucosal roughening	3	0
Oral mucosal scab	1	0
Oral pain	167	0
Oral pruritus	23	0
Paraesthesia oral	881	0
Pigmentation lip	1	0
<b>Oral soft tissue swelling and oedema</b>		
Lip oedema	4	0
Lip swelling	747	0
Mouth swelling	93	0
Oedema mouth	4	0
Palatal oedema	3	0
Palatal swelling	2	0
<b>Pancreatic disorders NEC</b>		
Pancreatic disorder	1	0
Pancreatic failure	1	0
Pancreatic mass	1	0
<b>Peptic ulcers and perforation</b>		
Peptic ulcer	1	0
Peptic ulcer haemorrhage	13	0
<b>Peritoneal and retroperitoneal disorders</b>		
Ascites	1	0
<b>Peritoneal and retroperitoneal fibrosis and adhesions</b>		
Abdominal adhesions	2	0
<b>Peritoneal and retroperitoneal haemorrhages</b>		
Haemoperitoneum	1	0
Retroperitoneal haemorrhage	1	1
<b>Rectal inflammations NEC</b>		
Proctitis	3	0
Proctitis ulcerative	1	0
<b>Salivary gland disorders NEC</b>		
Salivary gland disorder	1	0
Salivary gland pain	12	0
<b>Salivary gland enlargements</b>		
Parotid gland enlargement	10	0
Salivary gland enlargement	5	0
Submaxillary gland enlargement	7	0
<b>Salivary gland infections and inflammations</b>		
Noninfective sialoadenitis	1	0
<b>Stomatitis and ulceration</b>		
Aphthous ulcer	51	0
Lip ulceration	18	0
Mouth ulceration	437	0
Oral mucosa erosion	1	0
Palatal ulcer	1	0

## Case Series Drug Analysis Print

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Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Stomatitis	65	0
<b><i>Tongue disorders</i></b>		
Glossitis	20	0
Hypertrophy of tongue papillae	1	0
Plicated tongue	3	0
Tongue disorder	40	0
Tongue geographic	6	0
Tongue haemorrhage	3	0
Tongue ulceration	29	0
Trichoglossia	4	0
<b><i>Tongue signs and symptoms</i></b>		
Glossodynia	209	0
Scalloped tongue	5	0
Stiff tongue	4	0
Swollen tongue	477	0
Tongue blistering	19	0
Tongue coated	17	0
Tongue discolouration	37	0
Tongue discomfort	40	0
Tongue dry	15	0
Tongue eruption	9	0
Tongue erythema	13	0
Tongue exfoliation	1	0
Tongue movement disturbance	6	0
Tongue oedema	23	0
Tongue pruritus	2	0
Tongue rough	4	0
Tongue spasm	10	0
<b><i>Tooth missing</i></b>		
Tooth loss	6	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>36844</b>	<b>16</b>

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>General disorders</b>		
<b><i>Administration site reactions NEC</i></b>		
Administration site bruise	7	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	37	0
Puncture site pain	7	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
<b><i>Adverse effect absent</i></b>		
No adverse event	6	0
<b><i>Application and instillation site reactions</i></b>		
Application site acne	2	0
Application site bruise	10	0
Application site burn	1	0
Application site dryness	1	0
Application site erythema	17	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	8	0
<b><i>Asthenic conditions</i></b>		
Asthenia	1947	0
Chronic fatigue syndrome	75	0
Decreased activity	9	0
Fatigue	22144	0
Malaise	5128	1
Sluggishness	18	0



## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
<b><i>Body temperature altered</i></b>		
Hyperthermia	7	0
Hypothermia	25	0
Temperature regulation disorder	13	0
<b><i>Breast complications associated with device</i></b>		
Breast implant palpable	1	0
Capsular contracture associated with breast implant	1	0
<b><i>Cardiac complications associated with device</i></b>		
Prosthetic cardiac valve thrombosis	2	0
<b><i>Complications associated with device NEC</i></b>		
Capsular contracture associated with implant	1	0
Complication of device removal	3	0
Injury associated with device	4	0
Medical device pain	1	0
Medical device site swelling	1	0
Phantom shocks	2	0
<b><i>Death and sudden death</i></b>		
Brain death	3	3
Cardiac death	2	2
Clinical death	1	1
Death	184	184
Sudden death	27	27
<b><i>Febrile disorders</i></b>		
Hyperpyrexia	9	0
Pyrexia	14513	0
<b><i>Feelings and sensations NEC</i></b>		
Chills	9277	0
Feeling abnormal	1588	0
Feeling cold	1202	0
Feeling drunk	77	0
Feeling hot	1139	0
Feeling jittery	29	0
Feeling of body temperature change	318	0
Feeling of relaxation	3	0
Hangover	77	0
Hunger	47	0
Sensation of blood flow	4	0
Sensation of foreign body	54	0
Temperature intolerance	44	0
Thirst	335	0
Thirst decreased	1	0
<b><i>Fibrosis NEC</i></b>		
Fibrosis	1	0
<b><i>Gait disturbances</i></b>		
Gait disturbance	222	0
Gait inability	90	0
Loss of control of legs	23	0
<b><i>General signs and symptoms NEC</i></b>		
Adhesion	1	0
Chronic disease	1	0
Condition aggravated	230	0
Crepitations	3	0
Crying	149	0

## Case Series Drug Analysis Print

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Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Deformity	2	0
Discharge	12	0
Disease progression	2	0
Disease recurrence	29	0
Effusion	3	0
Energy increased	22	0
Exercise tolerance decreased	25	0
Exercise tolerance increased	1	0
Fat tissue increased	1	0
Foaming at mouth	3	0
General physical health deterioration	17	2
General symptom	3	0
Glassy eyes	6	0
High-pitched crying	3	0
Illness	1877	0
Induration	15	0
Influenza like illness	2352	0
Irritability postvaccinal	2	0
Local reaction	83	0
Moaning	3	0
Multiple organ dysfunction syndrome	10	4
Nonspecific reaction	2	0
Organ failure	2	1
Perforation	2	0
Peripheral swelling	3623	0
Physical deconditioning	2	0
Pre-existing condition improved	8	0
Prolapse	1	0
Screaming	20	0
Secretion discharge	24	0
Swelling	2915	0
Swelling face	805	0
Symptom recurrence	1	0
Terminal state	1	0
Tissue irritation	1	0
<b>Healing abnormal NEC</b>		
Impaired healing	3	0
<b>Implant and catheter site reactions</b>		
Implant site discolouration	2	0
Implant site pain	3	0
Implant site rash	1	0
Implant site swelling	2	0
Implant site urticaria	1	0
Implant site warmth	3	0
<b>Inflammations</b>		
Granuloma	1	0
Inflammation	478	0
Papillitis	1	0
Scar inflammation	3	0
Serositis	1	0
Systemic inflammatory response syndrome	2	0
<b>Infusion site reactions</b>		
Infusion site coldness	1	0

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Infusion site discolouration	1	0
Infusion site joint effusion	1	0
Infusion site joint pain	2	0
Infusion site mass	1	0
Infusion site nerve damage	1	0
Infusion site pain	4	0
Infusion site pruritus	2	0
Infusion site swelling	2	0
Infusion site urticaria	1	0
Infusion site warmth	2	0
<b>Injection site reactions</b>		
Injected limb mobility decreased	32	0
Injection site bruising	65	0
Injection site coldness	1	0
Injection site cyst	2	0
Injection site discolouration	5	0
Injection site discomfort	11	0
Injection site eczema	1	0
Injection site erythema	369	0
Injection site extravasation	1	0
Injection site haematoma	1	0
Injection site haemorrhage	6	0
Injection site hypersensitivity	2	0
Injection site hypoaesthesia	11	0
Injection site indentation	9	0
Injection site induration	4	0
Injection site inflammation	40	0
Injection site irritation	1	0
Injection site joint discomfort	2	0
Injection site joint erythema	3	0
Injection site joint movement impairment	1	0
Injection site joint pain	14	0
Injection site lymphadenopathy	1	0
Injection site macule	1	0
Injection site mass	532	0
Injection site movement impairment	1	0
Injection site muscle weakness	1	0
Injection site necrosis	4	0
Injection site nerve damage	1	0
Injection site nodule	1	0
Injection site oedema	16	0
Injection site pain	2856	0
Injection site paraesthesia	12	0
Injection site pruritus	200	0
Injection site rash	170	0
Injection site reaction	46	0
Injection site scab	4	0
Injection site scar	5	0
Injection site swelling	285	0
Injection site urticaria	29	0
Injection site vesicles	10	0
Injection site warmth	184	0
<b>Interactions</b>		

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Alcohol interaction	4	0
Drug interaction	27	0
Inhibitory drug interaction	3	0
<b>Mass conditions NEC</b>		
Cyst	43	0
Mass	68	0
Nodule	36	0
<b>Mucosal findings abnormal</b>		
Mucosa vesicle	1	0
Mucosal dryness	1	0
Mucosal haemorrhage	9	0
Mucosal inflammation	2	0
Oedema mucosal	1	0
Polyp	5	0
<b>Necrosis NEC</b>		
Fat necrosis	3	0
Necrosis	4	0
<b>Oedema NEC</b>		
Face oedema	31	0
Generalised oedema	4	0
Localised oedema	19	0
Oedema	73	0
Oedema peripheral	88	0
<b>Pain and discomfort NEC</b>		
Axillary pain	3071	0
Breakthrough pain	1	0
Chest discomfort	1667	0
Chest pain	4634	0
Discomfort	464	0
Facial discomfort	19	0
Facial pain	200	0
Inflammatory pain	17	0
Non-cardiac chest pain	30	0
Pain	8577	0
Suprapubic pain	1	0
Tenderness	656	0
Visceral pain	2	0
<b>Therapeutic and nontherapeutic responses</b>		
Adverse drug reaction	52	0
Adverse event	2	0
Adverse food reaction	3	0
Adverse reaction	6	0
Drug ineffective	305	0
Drug intolerance	4	0
Drug resistance	1	0
Immediate post-injection reaction	2	0
Inadequate analgesia	8	0
No reaction on previous exposure to drug	38	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

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Therapeutic response decreased	2	0
Therapeutic response unexpected	75	0
Therapy non-responder	1	0
Treatment failure	8	0
Vaccination failure	41	0
<b>Trophic disorders</b>		
Atrophy	2	0
Calcinosis	2	0
Hyperplasia	1	0
<b>Ulcers NEC</b>		
Ulcer	33	0
Ulcer haemorrhage	1	0
<b>Vaccination site reactions</b>		
Extensive swelling of vaccinated limb	14	0
Shoulder injury related to vaccine administration	34	0
Vaccination site anaesthesia	1	0
Vaccination site bruising	131	0
Vaccination site coldness	3	0
Vaccination site cyst	6	0
Vaccination site dermatitis	1	0
Vaccination site discolouration	15	0
Vaccination site discomfort	50	0
Vaccination site dryness	1	0
Vaccination site eczema	1	0
Vaccination site erythema	635	0
Vaccination site granuloma	5	0
Vaccination site haematoma	2	0
Vaccination site haemorrhage	24	0
Vaccination site hypersensitivity	4	0
Vaccination site hypoaesthesia	18	0
Vaccination site induration	75	0
Vaccination site inflammation	57	0
Vaccination site irritation	13	0
Vaccination site joint discomfort	3	0
Vaccination site joint erythema	11	0
Vaccination site joint inflammation	1	0
Vaccination site joint movement impairment	18	0
Vaccination site joint pain	32	0
Vaccination site joint swelling	4	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	8	0
Vaccination site macule	1	0
Vaccination site mass	282	0
Vaccination site movement impairment	90	0
Vaccination site nerve damage	1	0
Vaccination site nodule	4	0
Vaccination site oedema	3	0
Vaccination site pain	2148	0
Vaccination site paraesthesia	9	0
Vaccination site phlebitis	1	0
Vaccination site photosensitivity reaction	1	0
Vaccination site pruritus	170	0
Vaccination site rash	134	0

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Vaccination site reaction	34	0
Vaccination site scab	2	0
Vaccination site scar	1	0
Vaccination site swelling	581	0
Vaccination site thrombosis	1	0
Vaccination site ulcer	1	0
Vaccination site urticaria	10	0
Vaccination site vesicles	9	0
Vaccination site warmth	273	0
<b><i>Vascular complications associated with device</i></b>		
Vascular stent thrombosis	1	0
<b><i>Withdrawal and rebound effects</i></b>		
Drug withdrawal syndrome	4	0
Withdrawal syndrome	47	0
<b>General disorders SOC TOTAL</b>	<b>101890</b>	<b>225</b>

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i><b>Bile duct infections and inflammations</b></i>		
Biliary colic	12	0
Cholangitis	1	0
<i><b>Cholecystitis and cholelithiasis</b></i>		
Cholecystitis	3	0
Cholecystitis acute	2	0
Cholelithiasis	10	0
<i><b>Cholestasis and jaundice</b></i>		
Cholestasis	2	0
Jaundice	23	0
Jaundice cholestatic	10	0
Ocular icterus	2	0
<i><b>Gallbladder disorders NEC</b></i>		
Gallbladder disorder	2	0
<i><b>Hepatic and hepatobiliary disorders NEC</b></i>		
Liver disorder	14	0
<i><b>Hepatic enzymes and function abnormalities</b></i>		
Hepatic function abnormal	6	0
<i><b>Hepatic failure and associated disorders</b></i>		
Acute hepatic failure	1	0
Hepatic failure	2	1
<i><b>Hepatic fibrosis and cirrhosis</b></i>		
Hepatic cirrhosis	1	0
<i><b>Hepatic vascular disorders</b></i>		
Congestive hepatopathy	2	0
Hepatic artery embolism	1	0
Hepatic haemorrhage	2	0
Hepatic vein thrombosis	5	0
Portal vein thrombosis	7	0
<i><b>Hepatobiliary signs and symptoms</b></i>		
Hepatic pain	27	0
Hepatomegaly	3	0
Liver tenderness	3	0
<i><b>Hepatocellular damage and hepatitis NEC</b></i>		
Autoimmune hepatitis	10	0
Drug-induced liver injury	3	0
Hepatic steatosis	4	0
Hepatitis	12	0
Hepatitis acute	2	0
Immune-mediated hepatic disorder	1	0
Liver injury	22	0
<b>Hepatic disorders SOC TOTAL</b>	<b>195</b>	<b>1</b>

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i><b>Acute and chronic sarcoidosis</b></i>		
Sarcoidosis	16	0
<i><b>Allergic conditions NEC</b></i>		
Allergic oedema	15	0
Allergy to animal	2	0
Allergy to arthropod bite	6	0
Allergy to arthropod sting	2	0
Allergy to metals	2	0
Allergy to sting	1	0
Hypersensitivity	962	0
Infusion related hypersensitivity reaction	3	0
Mite allergy	2	0
Multiple allergies	11	0
Serum sickness	2	0
Serum sickness-like reaction	5	0
Type I hypersensitivity	1	0
Type III immune complex mediated reaction	4	0
Type IV hypersensitivity reaction	6	0
<i><b>Allergies to foods, food additives, drugs and other chemicals</b></i>		
Allergic reaction to excipient	5	0
Allergy to chemicals	3	0
Allergy to vaccine	41	0
Contrast media reaction	2	0
Drug hypersensitivity	28	0
Food allergy	27	0
Milk allergy	2	0
Oral allergy syndrome	2	0
Reaction to colouring	1	0
Reaction to excipient	9	0
Reaction to preservatives	5	0
Rubber sensitivity	1	0
Smoke sensitivity	1	0
<i><b>Anaphylactic and anaphylactoid responses</b></i>		
Anaphylactic reaction	493	2
Anaphylactic shock	54	0
Anaphylactoid reaction	21	0
Anaphylactoid shock	4	0
<i><b>Atopic disorders</b></i>		
Atopy	2	0
Seasonal allergy	104	0
<i><b>Autoimmune disorders NEC</b></i>		
Autoimmune disorder	44	0
<i><b>Immune and associated conditions NEC</b></i>		
Anamnestic reaction	1	0
Bacille Calmette-Guerin scar reactivation	53	0
Cytokine storm	1	0
Decreased immune responsiveness	3	0
Graft versus host disease	2	0
Haemophagocytic lymphohistiocytosis	2	0
Immune reconstitution inflammatory syndrome	1	0
Immune system disorder	28	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: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Immune system disorders cont'd</i>		
Multisystem inflammatory syndrome in children	3	0
Sensitisation	6	0
Systemic immune activation	2	0
<b><i>Immunodeficiency disorders NEC</i></b>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	2	0
Immunosuppression	3	0
<b><i>Transplant rejections</i></b>		
Corneal graft rejection	9	0
Kidney transplant rejection	1	0
Solid organ transplant rejection	1	0
Transplant rejection	2	0
<b>Immune system disorders SOC TOTAL</b>	<b>2018</b>	<b>2</b>

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Infections</b>		
<b><i>Abdominal and gastrointestinal infections</i></b>		
Abdominal abscess	2	0
Abdominal infection	1	0
Anal abscess	3	0
Appendicitis	40	0
Appendicitis perforated	7	0
Diverticulitis	13	0
Dysentery	1	0
Gastric infection	2	0
Gastroenteritis	26	0
Mesenteric abscess	1	0
Peritonitis	3	1
Rectal abscess	1	0
<b><i>Adenoviral infections</i></b>		
Adenoviral conjunctivitis	1	0
Adenovirus infection	1	0
<b><i>Aspergillus infections</i></b>		
Bronchopulmonary aspergillosis	1	0
<b><i>Bacterial infections NEC</i></b>		
Abscess bacterial	2	0
Arthritis bacterial	4	0
Bacterial colitis	1	0
Bacterial diarrhoea	1	0
Bacterial infection	15	0
Bacterial sepsis	1	0
Bacterial vaginosis	1	0
Cellulitis	182	0
Conjunctivitis bacterial	1	0
Ear infection bacterial	1	0
External ear cellulitis	1	0
Folliculitis	16	0
Gangrene	1	0
Gastrointestinal bacterial overgrowth	1	0
Injection site cellulitis	2	0
Meningitis bacterial	3	0
Paronychia	3	0
Perichondritis	2	0
Periorbital cellulitis	2	0
Pneumonia bacterial	1	0
Sinusitis bacterial	2	0
Skin bacterial infection	4	0
Tonsillitis bacterial	3	0
Urinary tract infection bacterial	1	0
Vaccination site cellulitis	20	0
Zoonotic bacterial infection	1	1
<b><i>Bartonella infections</i></b>		
Cat scratch disease	1	0
<b><i>Bone and joint infections</i></b>		
Abscess jaw	1	0
Arthritis infective	1	0
Osteomyelitis	2	0
<b><i>Borrelial infections</i></b>		
Lyme disease	2	0

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Infections</b> Infections cont'd		
Relapsing fever	1	0
<b>Breast infections</b>		
Breast abscess	3	0
Mastitis	78	0
<b>Caliciviral infections</b>		
Gastroenteritis norovirus	3	0
<b>Campylobacter infections</b>		
Campylobacter gastroenteritis	1	0
Campylobacter infection	1	0
<b>Candida infections</b>		
Anal candidiasis	3	0
Balanitis candida	1	0
Candida infection	63	0
Oral candidiasis	37	0
Respiratory moniliasis	1	0
Skin candida	2	0
Systemic candida	1	0
Urinary tract candidiasis	1	0
Vulvovaginal candidiasis	48	0
<b>Cardiac infections</b>		
Cardiac infection	1	0
Cardiac valve vegetation	1	0
Pericarditis infective	2	0
<b>Central nervous system and spinal infections</b>		
Brain abscess	1	0
CNS ventriculitis	1	0
Cavernous sinus thrombosis	1	0
Encephalitis	18	0
Encephalomyelitis	1	0
Meningitis	8	0
Meningitis aseptic	3	0
Myelitis	8	0
Subdural abscess	1	0
<b>Clostridia infections</b>		
Clostridium difficile infection	2	0
<b>Coronavirus infections</b>		
Asymptomatic COVID-19	15	0
COVID-19	1454	43
COVID-19 pneumonia	50	14
Coronavirus infection	7	0
Post-acute COVID-19 syndrome	2	0
Severe acute respiratory syndrome	4	0
Suspected COVID-19	68	4
<b>Corynebacteria infections</b>		
Diphtheria	2	0
<b>Coxiella infections</b>		
Q fever	12	0
<b>Cytomegaloviral infections</b>		
Cytomegalovirus infection	2	0
Cytomegalovirus syndrome	1	0
<b>Dental and oral soft tissue infections</b>		
Abscess oral	6	0
Gingivitis	12	0

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
Oral infection	1	0
Parotitis	11	0
Pericoronitis	2	0
Pulpitis dental	1	0
Sialoadenitis	3	0
Tongue abscess	1	0
Tooth abscess	8	0
Tooth infection	9	0
<b>Ear infections</b>		
Ear infection	90	0
Labyrinthitis	101	0
Mastoiditis	1	0
Otitis externa	3	0
Otitis media	3	0
Otitis media acute	1	0
Otitis media chronic	4	0
<b>Ectoparasitic infestations</b>		
Acarodermatitis	4	0
Bed bug infestation	1	0
<b>Epstein-Barr viral infections</b>		
Epstein-Barr virus infection	3	0
Epstein-Barr virus infection reactivation	1	0
Infectious mononucleosis	27	0
<b>Escherichia infections</b>		
Escherichia bacteraemia	1	0
<b>Eye and eyelid infections</b>		
Conjunctivitis	71	0
Eye abscess	1	0
Eye infection	23	0
Eye infection intraocular	1	0
Eyelid boil	2	0
Eyelid infection	2	0
Hordeolum	27	0
Keratouveitis	1	0
Periorbital infection	2	0
<b>Female reproductive tract infections</b>		
Bartholin's abscess	1	0
Bartholinitis	1	0
Endometritis	3	0
Funisitis	1	0
Pelvic inflammatory disease	2	0
Vaginal infection	1	0
Vulval abscess	1	0
Vulvitis	1	0
<b>Fungal infections NEC</b>		
Fungal infection	18	0
Fungal skin infection	5	0
Onychomycosis	2	0
Oral fungal infection	2	0
Pneumonia fungal	2	0
Vulvovaginal mycotic infection	7	0
<b>Hepatitis virus infections</b>		
Hepatitis A	1	0

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Infections</b> Infections cont'd		
Hepatitis E	1	0
<b><i>Hepatobiliary and spleen infections</i></b>		
Biliary sepsis	3	0
Cholecystitis infective	2	0
Hepatic infection	1	0
<b><i>Herpes viral infections</i></b>		
Eczema herpeticum	2	0
Genital herpes	86	0
Genital herpes simplex	6	0
Genital herpes zoster	1	0
Herpes ophthalmic	3	0
Herpes simplex	26	0
Herpes simplex encephalitis	1	1
Herpes simplex reactivation	2	0
Herpes virus infection	13	0
Herpes zoster	1417	0
Herpes zoster disseminated	1	0
Herpes zoster meningoencephalitis	1	0
Herpes zoster oticus	15	0
Herpes zoster reactivation	1	0
Meningitis herpes	1	0
Nasal herpes	4	0
Ophthalmic herpes simplex	2	0
Ophthalmic herpes zoster	4	0
Oral herpes	307	0
Varicella	30	0
Varicella zoster virus infection	2	0
<b><i>Infections NEC</i></b>		
Abscess	35	0
Abscess limb	9	0
Abscess soft tissue	1	0
Catheter site infection	1	0
Genital abscess	2	0
Infected bite	3	0
Infected cyst	2	0
Infection	233	0
Infection susceptibility increased	2	0
Injection site abscess	1	0
Injection site infection	5	0
Localised infection	32	0
Lymph gland infection	13	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	11	0
Vaccination site infection	13	0
Vaccine breakthrough infection	23	0
Vestibulitis	2	0
Wound infection	2	0
<b><i>Infectious transmissions</i></b>		
Secondary transmission	8	0

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Infections</b> Infections cont'd		
Vaccine virus shedding	1	0
<b><i>Influenza viral infections</i></b>		
Influenza	1584	0
<b><i>Klebsiella infections</i></b>		
Klebsiella infection	1	0
<b><i>Lower respiratory tract and lung infections</i></b>		
Bronchitis	22	0
Infectious pleural effusion	1	0
Lower respiratory tract infection	233	8
Pneumonia	138	13
Pneumonia aspiration	9	6
Sputum purulent	1	0
<b><i>Male reproductive tract infections</i></b>		
Epididymitis	8	0
Orchitis	5	0
Prostate infection	2	0
<b><i>Molluscum contagiosum viral infections</i></b>		
Molluscum contagiosum	1	0
<b><i>Mumps viral infections</i></b>		
Mumps	7	0
<b><i>Muscle and soft tissue infections</i></b>		
Abscess neck	1	0
Infective tenosynovitis	1	0
Necrotising fasciitis	2	0
Psoas abscess	1	0
Soft tissue infection	2	0
<b><i>Neisseria infections</i></b>		
Gonorrhoea	1	0
Meningococcal bacteraemia	1	0
<b><i>Orthopox viral infections</i></b>		
Vaccinia virus infection	1	0
<b><i>Plasmodia infections</i></b>		
Malaria	2	0
<b><i>Pneumocystis infections</i></b>		
Pneumocystis jirovecii pneumonia	2	0
<b><i>Retroviral infections</i></b>		
Acquired immunodeficiency syndrome	1	0
HIV infection	2	0
Persistent generalised lymphadenopathy	1	0
<b><i>Rhinoviral infections</i></b>		
Rhinovirus infection	1	0
<b><i>Rotaviral infections</i></b>		
Gastroenteritis rotavirus	1	0
<b><i>Rubeola viral infections</i></b>		
Measles	4	0
<b><i>Salmonella infections</i></b>		
Typhoid fever	1	0
<b><i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i></b>		
Neutropenic sepsis	3	1
Sepsis	52	7
Sepsis syndrome	2	0
Septic rash	1	0
Septic shock	6	1

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
Urosepsis	5	0
<b><i>Skin structures and soft tissue infections</i></b>		
Abscess sweat gland	1	0
Acne pustular	1	0
Blister infected	1	0
Dermatitis infected	3	0
Impetigo	11	0
Infected skin ulcer	1	0
Injection site pustule	2	0
Nail infection	2	0
Pustule	18	0
Pyoderma	1	0
Rash pustular	12	0
Skin infection	32	0
Subcutaneous abscess	11	0
Sweat gland infection	1	0
Vaccination site pustule	4	0
<b><i>Staphylococcal infections</i></b>		
Furuncle	39	1
Pneumonia staphylococcal	1	0
Staphylococcal abscess	1	0
Staphylococcal infection	4	0
Staphylococcal sepsis	1	0
<b><i>Streptococcal infections</i></b>		
Meningitis pneumococcal	1	0
Pharyngitis streptococcal	6	0
Streptococcal abscess	1	0
Streptococcal endocarditis	1	0
Streptococcal infection	1	0
Streptococcal sepsis	1	0
<b><i>Tinea infections</i></b>		
Body tinea	3	0
Tinea infection	1	0
Tinea pedis	3	0
Tinea versicolour	4	0
<b><i>Treponema infections</i></b>		
Syphilis	2	0
<b><i>Trypanosomal infections</i></b>		
African trypanosomiasis	3	0
<b><i>Tuberculous infections</i></b>		
Lymph node tuberculosis	1	0
Pulmonary tuberculosis	1	0
Tuberculosis	1	0
Tuberculosis of central nervous system	1	0
<b><i>Upper respiratory tract infections</i></b>		
Acute sinusitis	4	0
Chronic sinusitis	3	0
Croup infectious	1	0
Epiglottitis	1	0
Laryngitis	30	0
Nasopharyngitis	1032	1
Peritonsillar abscess	4	0
Pharyngitis	30	0

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Infections</b> Infections cont'd		
Rhinitis	44	0
Sinusitis	158	0
Tonsillitis	120	0
Tracheitis	4	0
Tracheostomy infection	1	0
Upper respiratory tract infection	12	0
<b>Urinary tract infections</b>		
Cystitis	75	0
Kidney infection	44	0
Pyelonephritis	2	0
Urethritis	1	0
Urinary tract infection	197	0
<b>Vascular infections</b>		
Haematoma infection	1	0
Infected lymphocele	2	0
Infusion site infection	1	0
Lymphangitis	9	0
<b>Viral infections NEC</b>		
Arthritis viral	1	0
Conjunctivitis viral	2	0
Ear infection viral	1	0
Encephalitis viral	6	1
Eye infection viral	2	0
Gastroenteritis viral	30	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	45	0
Sweating fever	104	0
Vestibular neuronitis	30	0
Viral diarrhoea	2	0
Viral infection	53	0
Viral labyrinthitis	4	0
Viral myocarditis	3	0
Viral pericarditis	3	0
Viral pharyngitis	20	0
Viral rash	56	0
Viral sinusitis	1	0
Viral tonsillitis	2	0
<b>Infections SOC TOTAL</b>	<b>9554</b>	<b>104</b>



## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Injuries</b>		
<b><i>Abdominal and gastrointestinal injuries NEC</i></b>		
Gallbladder injury	1	0
Liver contusion	1	0
Mouth injury	3	0
Oral contusion	5	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
<b><i>Accidental exposures to product</i></b>		
Accidental exposure to product	20	0
<b><i>Anaesthetic and allied procedural complications</i></b>		
Airway complication of anaesthesia	2	0
Delayed recovery from anaesthesia	2	0
Sedation complication	1	0
<b><i>Atmospheric pressure injuries</i></b>		
Barotitis media	1	0
Hypobarism	1	0
<b><i>Bone and joint injuries NEC</i></b>		
Bursa injury	2	0
Joint injury	8	0
Meniscus injury	1	0
<b><i>Cardiac and vascular procedural complications</i></b>		
Shunt blood flow excessive	1	0
Vascular pseudoaneurysm	1	0
<b><i>Cardiovascular injuries</i></b>		
Vascular injury	8	0
<b><i>Cerebral injuries NEC</i></b>		
Brain contusion	4	0
Brain herniation	2	0
Concussion	4	0
Craniocerebral injury	1	0
Subarachnoid haematoma	1	0
Subdural haematoma	5	0
Subdural haemorrhage	5	0
Traumatic intracranial haemorrhage	1	1
<b><i>Chemical injuries</i></b>		
Chemical burn of skin	7	0
Chemical cystitis	2	0
<b><i>Chest and respiratory tract injuries NEC</i></b>		
Bronchial injury	1	0
Chest crushing	10	0
Foreign body in throat	1	0
Traumatic lung injury	1	0
<b><i>Conditions caused by cold</i></b>		
Chillblains	57	0
Cold shock response	1	0
Frostbite	1	0
<b><i>Cranial nerve injuries</i></b>		
Vth nerve injury	1	0
<b><i>Ear injuries NEC</i></b>		

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Injuries</b> <span style="float: right;">Injuries cont'd</span>		
Deafness traumatic	1	0
Ear injury	1	0
<b>Exposures associated with pregnancy, delivery and lactation</b>		
Exposure during pregnancy	11	0
Exposure via breast milk	140	0
Foetal exposure during pregnancy	50	0
Foetal exposure timing unspecified	1	0
Maternal exposure before pregnancy	17	0
Maternal exposure during breast feeding	1652	0
Maternal exposure during delivery	1	0
Maternal exposure during pregnancy	899	0
Maternal exposure timing unspecified	11	0
Paternal exposure before pregnancy	3	0
<b>Exposures to agents or circumstances NEC</b>		
Exposure to SARS-CoV-2	3	0
Exposure to vaccinated person	4	0
<b>Eye and ear procedural complications</b>		
Toxic anterior segment syndrome	1	0
<b>Eye injuries NEC</b>		
Corneal abrasion	1	0
Eye contusion	13	0
Eye injury	24	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
<b>Foetal and neonatal conditions associated with product exposure</b>		
Intoxication by breast feeding	1	0
<b>Fractures and dislocations NEC</b>		
Bone fragmentation	1	0
Fracture	4	0
Joint dislocation	3	0
Multiple fractures	1	0
<b>Gastrointestinal and hepatobiliary procedural complications</b>		
Post procedural constipation	1	0
Postoperative ileus	1	0
Procedural nausea	10	0
Procedural vomiting	2	0
<b>Heat injuries (excl thermal burns)</b>		
Heat cramps	2	0
Heat exhaustion	3	0
Heat illness	1	0
Heat oedema	14	0
Heat stroke	3	0
<b>Intentional product use issues</b>		
Intentional dose omission	1	0
Intentional product use issue	1	0
<b>Limb fractures and dislocations</b>		
Atypical femur fracture	1	0
Clavicle fracture	27	0
Femoral neck fracture	1	0
Femur fracture	1	0

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Injuries</b> <span style="float: right;">Injuries cont'd</span>		
Fibula fracture	1	0
Hip fracture	2	0
Tibia fracture	1	0
Upper limb fracture	1	0
Wrist fracture	1	0
<b>Medication errors, product use errors and issues NEC</b>		
Circumstance or information capable of leading to medication error	2	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	3	0
Product use complaint	1	0
Product use issue	24	0
Vaccination error	6	0
Wrong dose	4	0
Wrong drug	11	0
Wrong schedule	1	0
Wrong technique in product usage process	5	0
<b>Muscle, tendon and ligament injuries</b>		
Epicondylitis	20	0
Ligament injury	2	0
Ligament sprain	9	0
Mallet finger	1	0
Muscle injury	31	0
Muscle rupture	8	0
Muscle strain	30	0
Post-traumatic neck syndrome	2	0
Tendon injury	7	0
Tendon rupture	22	0
<b>Musculoskeletal procedural complications</b>		
Periprosthetic osteolysis	1	0
Post laminectomy syndrome	1	0
<b>Nerve injuries NEC</b>		
Nerve injury	95	0
<b>Neurological and psychiatric procedural complications</b>		
Post lumbar puncture syndrome	1	0
Post procedural stroke	1	0
Procedural dizziness	11	0
<b>Non-occupational environmental exposures</b>		
Exposure to extreme temperature	2	0
<b>Non-site specific injuries NEC</b>		
Animal scratch	1	0
Arthropod bite	5	0
Arthropod sting	5	0
Bite	1	0
Crush injury	1	0
Electric shock	18	0
Fall	186	0
Foreign body	2	0
Injury	11	0
Multiple injuries	2	0
Nervous system injury	2	0
Post concussion syndrome	1	0

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Injuries</b> <span style="float: right;">Injuries cont'd</span>		
Traumatic haematoma	1	0
Wound	7	0
Wound complication	10	0
Wound haematoma	1	0
Wound haemorrhage	2	0
Wound secretion	5	0
<b>Non-site specific procedural complications</b>		
Incision site pain	3	0
Infusion related reaction	7	0
Injection related reaction	63	0
Post procedural complication	5	0
Post procedural erythema	1	0
Post procedural inflammation	1	0
Post procedural pruritus	1	0
Procedural pain	2	0
Seroma	1	0
<b>Occupational exposures</b>		
Occupational exposure to SARS-CoV-2	1	0
Occupational exposure to product	1	0
<b>Off label uses</b>		
Off label use	258	0
<b>Overdoses NEC</b>		
Overdose	51	0
<b>Pathways and sources of exposure</b>		
Exposure via unknown route	1	0
<b>Pelvic fractures and dislocations</b>		
Pelvic fracture	1	0
<b>Peripheral nerve injuries</b>		
Axillary nerve injury	1	0
Brachial plexus injury	1	0
Sciatic nerve injury	2	0
Ulnar nerve injury	4	0
<b>Poisoning and toxicity</b>		
Alcohol poisoning	1	0
Poisoning	12	0
Toxicity to various agents	3	0
<b>Product administration errors and issues</b>		
Accidental overdose	8	0
Contraindicated product administered	1	0
Duplicate therapy error	1	0
Expired product administered	12	0
Extra dose administered	1	0
Inappropriate schedule of product administration	595	0
Incomplete course of vaccination	2	0
Incorrect dose administered	52	0
Incorrect drug administration rate	1	0
Incorrect product formulation administered	2	0
Incorrect route of product administration	6	0
Lack of vaccination site rotation	1	0
Poor quality product administered	3	0
Product administered at inappropriate site	18	0
Product administered to patient of inappropriate age	1	0
Product administration error	8	0

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Injuries</b> <span style="float: right;">Injuries cont'd</span>		
Product dose omission issue	6	0
Wrong product administered	20	0
<b>Product confusion errors and issues</b>		
Product dosage form confusion	1	0
Product label confusion	3	0
<b>Product dispensing errors and issues</b>		
Product dispensing error	4	0
<b>Product monitoring errors and issues</b>		
Drug monitoring procedure incorrectly performed	1	0
<b>Product preparation errors and issues</b>		
Product preparation error	3	0
Product preparation issue	6	0
<b>Product prescribing errors and issues</b>		
Contraindicated product prescribed	2	0
Product prescribing error	2	0
<b>Product selection errors and issues</b>		
Product selection error	2	0
<b>Radiation injuries</b>		
Sunburn	22	0
<b>Renal and urinary tract injuries NEC</b>		
Bladder injury	1	0
Foreign body in urogenital tract	1	0
<b>Reproductive system and breast injuries</b>		
Penile contusion	1	0
Penis injury	1	0
<b>Site specific injuries NEC</b>		
Back injury	2	0
Face crushing	3	0
Face injury	1	0
Head injury	33	0
Limb crushing injury	4	0
Limb injury	121	0
Nasal injury	1	0
Neck crushing	1	0
Neck injury	1	0
Pharyngeal contusion	1	0
<b>Site specific procedural complications NEC</b>		
Axillary web syndrome	2	0
<b>Skin injuries NEC</b>		
Contusion	1189	0
Hair injury	1	0
Nail avulsion	1	0
Scar	22	0
Scratch	7	0
Skin abrasion	6	0
Skin injury	4	0
Skin laceration	3	0
Skin wound	3	0
Splinter	1	0
Subcutaneous haematoma	2	0
<b>Skin procedural complications</b>		
Dermal filler overcorrection	1	0
Recall phenomenon	1	0

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Injuries</b> <span style="float: right;">Injuries cont'd</span>		
<b><i>Skull fractures, facial bone fractures and dislocations</i></b>		
Facial bones fracture	1	0
Fractured skull depressed	1	0
<b><i>Spinal cord injuries NEC</i></b>		
Spinal cord injury cervical	1	0
<b><i>Spinal fractures and dislocations</i></b>		
Spinal fracture	5	0
<b><i>Stoma complications</i></b>		
Gastrointestinal stoma complication	2	0
Stoma site discharge	1	0
Stoma site extravasation	1	0
Stoma site haemorrhage	1	0
<b><i>Thermal burns</i></b>		
Airway burns	1	0
Burn oesophageal	4	0
Burn of internal organs	4	0
Burn oral cavity	5	0
Burns second degree	6	0
Burns third degree	5	0
Thermal burn	20	0
Thermal burns of eye	15	0
<b><i>Underdoses NEC</i></b>		
Underdose	6	0
<b><i>Vaccination related complications</i></b>		
Adverse event following immunisation	1	0
Post vaccination syndrome	1	0
Vaccination complication	50	0
<b>Injuries SOC TOTAL</b>	<b>6437</b>	<b>1</b>

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Investigations</b>		
<b><i>Adrenal cortex tests</i></b>		
Cortisol decreased	4	0
<b><i>Adrenal medulla tests</i></b>		
Epinephrine abnormal	1	0
Epinephrine increased	1	0
<b><i>Auditory and vestibular diagnostic procedures</i></b>		
Acoustic stimulation tests	5	0
Audiogram abnormal	1	0
<b><i>Autoimmunity analyses</i></b>		
Antinuclear antibody	1	0
Antinuclear antibody increased	1	0
Antinuclear antibody positive	1	0
Rheumatoid factor	3	0
<b><i>Bacteria identification and serology (excl mycobacteria)</i></b>		
Bacterial test positive	1	0
<b><i>Blood counts NEC</i></b>		
Full blood count	5	0
Full blood count abnormal	2	0
<b><i>Blood gas and acid base analyses</i></b>		
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	7	0
Blood pH abnormal	1	0
Blood pH increased	12	0
Oxygen consumption	1	0
Oxygen consumption decreased	2	0
Oxygen saturation	8	0
Oxygen saturation abnormal	1	0
Oxygen saturation decreased	77	0
PO2 decreased	1	0
Venous oxygen saturation decreased	1	0
<b><i>Bone marrow and immune tissue histopathology procedures</i></b>		
Aspiration bone marrow	1	0
Biopsy lymph gland	1	0
<b><i>Bone marrow and immune tissue imaging procedures</i></b>		
Lymph nodes scan abnormal	1	0
Scan lymph nodes	4	0
<b><i>Carbohydrate tolerance analyses (incl diabetes)</i></b>		
Blood glucose	9	0
Blood glucose abnormal	12	0
Blood glucose decreased	34	0
Blood glucose fluctuation	16	0
Blood glucose increased	102	0
Blood glucose normal	1	0
Glycosylated haemoglobin increased	1	0
<b><i>Cardiac auscultatory investigations</i></b>		
Cardiac murmur	38	0
Heart sounds	6	0
Heart sounds abnormal	4	0
<b><i>Cardiac function diagnostic procedures</i></b>		
Cardiac monitoring	1	0

## Case Series Drug Analysis Print

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Report Run Date: 10-Dec-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Investigations</b>		
Investigations cont'd		
Cardiac output	1	0
Central venous pressure	1	0
Echocardiogram	1	0
Ejection fraction decreased	2	0
Myocardial strain imaging	1	0
Right atrial volume abnormal	1	0
Stroke volume decreased	1	0
<b>Cardiac imaging procedures</b>		
Magnetic resonance imaging heart	1	0
Scan myocardial perfusion abnormal	1	0
<b>Cell marker analyses</b>		
Carcinoembryonic antigen increased	1	0
HLA-B*27 positive	1	0
Prostatic specific antigen increased	2	0
<b>Central nervous system imaging procedures</b>		
Computerised tomogram head	7	0
Magnetic resonance imaging head	12	0
Magnetic resonance imaging head abnormal	1	0
<b>Cerebrospinal fluid tests (excl microbiology)</b>		
CSF pressure	1	0
<b>Chemistry analyses NEC</b>		
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
<b>Cholesterol analyses</b>		
Blood cholesterol increased	10	0
Remnant-like lipoprotein particles	3	0
<b>Coagulation and bleeding analyses</b>		
Activated partial thromboplastin time prolonged	15	0
Activated partial thromboplastin time shortened	1	0
Bleeding time	1	0
Bleeding time abnormal	1	0
Bleeding time prolonged	9	0
Blood thromboplastin	1	0
Clot retraction	1	1
Coagulation factor VIII level decreased	1	0
Coagulation time prolonged	9	0
Coagulation time shortened	4	0
Fibrin D dimer increased	16	0
International normalised ratio abnormal	8	0
International normalised ratio decreased	22	0
International normalised ratio fluctuation	3	0
International normalised ratio increased	52	0
Platelet factor 4	1	0
Prothrombin time prolonged	1	0
Prothrombin time shortened	1	0
<b>Digestive enzymes</b>		
Amylase increased	1	0
<b>ECG investigations</b>		
Electrocardiogram	5	0



## Case Series Drug Analysis Print

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Report Run Date: 10-Dec-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Investigations</b>		
Investigations cont'd		
Electrocardiogram QRS complex prolonged	1	0
Electrocardiogram QT prolonged	10	0
Electrocardiogram ST segment depression	2	0
Electrocardiogram ST segment elevation	10	0
Electrocardiogram ST-T segment abnormal	2	0
Electrocardiogram T wave inversion	5	0
Electrocardiogram abnormal	19	0
Electrocardiogram change	1	0
Electrocardiogram normal	2	0
Electrocardiogram repolarisation abnormality	1	0
QRS axis abnormal	1	0
<b>Endocrine analyses and imaging NEC</b>		
Hormone level abnormal	53	0
<b>Faecal analyses NEC</b>		
Faecal calprotectin	2	0
Faecal calprotectin increased	4	0
<b>Fertility analyses</b>		
Infertility tests	1	0
Semen analysis abnormal	1	0
Sperm concentration	2	0
Sperm concentration decreased	1	0
Spermatozoa abnormal	1	0
<b>Foetal and neonatal diagnostic procedures</b>		
Foetal heart rate abnormal	4	2
Foetal heart rate increased	1	0
Foetal monitoring	1	0
Foetal non-stress test	1	0
<b>Gastrointestinal and abdominal imaging procedures</b>		
Computerised tomogram abdomen	1	0
Sigmoidoscopy abnormal	1	0
X-ray with contrast upper gastrointestinal tract	1	0
<b>Gastrointestinal function diagnostic procedures</b>		
Gastric pH decreased	1	0
<b>Gastrointestinal, pancreatic and APUD hormone analyses</b>		
Blood insulin	2	0
Blood insulin decreased	1	0
<b>Haematological analyses NEC</b>		
Blood viscosity abnormal	1	0
Blood viscosity decreased	1	0
Plasma viscosity	1	0
Plasma viscosity abnormal	1	0
Red blood cell sedimentation rate increased	6	0
<b>Heart rate and pulse investigations</b>		
Carotid pulse	1	0
Heart rate	431	0
Heart rate abnormal	61	0
Heart rate decreased	86	0
Heart rate increased	936	0
Heart rate irregular	226	0
Heart rate normal	1	0
Maximum heart rate	2	0
Pulse abnormal	18	0
Pulse absent	1	0

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Pulse pressure increased	1	0
Radial pulse abnormal	1	0
Sinus rhythm	7	0
<b>Hepatobiliary imaging procedures</b>		
Liver scan	1	0
<b>Imaging procedures NEC</b>		
Computerised tomogram	4	0
Magnetic resonance imaging	4	0
Magnetic resonance imaging abnormal	1	0
Scan	2	0
X-ray	1	0
<b>Immune response protein analyses NEC</b>		
Cytokine test	1	0
<b>Immunoglobulin analyses</b>		
Blood immunoglobulin G increased	1	0
Blood immunoglobulin M	1	0
Blood immunoglobulin M increased	1	0
<b>Immunology analyses NEC</b>		
Antibody test	4	0
Immunology test	12	0
<b>Immunology skin tests NEC</b>		
Allergy alert test	1	0
Skin test positive	1	0
<b>Investigations NEC</b>		
Blood test	24	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
<b>Liver function analyses</b>		
Alanine aminotransferase increased	25	0
Aspartate aminotransferase	1	0
Aspartate aminotransferase abnormal	1	0
Aspartate aminotransferase increased	2	0
Blood bilirubin increased	4	0
Gamma-glutamyltransferase increased	5	0
Hepatic enzyme increased	7	0
Liver function test	1	0
Liver function test abnormal	30	0
Liver function test increased	24	0
Transaminases increased	5	0
<b>Metabolism tests NEC</b>		
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
<b>Microbiology and serology tests NEC</b>		

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Culture negative	1	0
Culture throat	1	0
Culture urine	1	0
Vaccine induced antibody absent	1	0
<b>Mineral and electrolyte analyses</b>		
Blood calcium increased	1	0
Blood copper increased	1	0
Blood iron	1	0
Blood iron decreased	9	0
Blood iron increased	1	0
Blood magnesium decreased	1	0
Blood phosphorus decreased	1	0
Blood phosphorus increased	1	0
Blood potassium abnormal	1	0
Blood potassium decreased	4	0
Blood potassium increased	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	2	0
<b>Musculoskeletal and soft tissue imaging procedures</b>		
Skull X-ray	6	0
<b>Musculoskeletal and soft tissue tests NEC</b>		
Swollen joint count increased	1	0
<b>Mycobacteria identification and serology</b>		
Tuberculin test positive	1	0
<b>Neurologic diagnostic procedures</b>		
Coma scale abnormal	5	0
Hoover's sign of leg paresis	1	0
Joint position sense decreased	1	0
Lumbar puncture	6	0
Magnetic resonance neurography	1	0
Temperature perception test abnormal	1	0
Temperature perception test increased	1	0
<b>Ophthalmic function diagnostic procedures</b>		
Corneal reflex decreased	1	0
Intraocular pressure increased	7	0
Intraocular pressure test	2	0
Visual acuity tests	1	0
<b>Physical examination procedures and organ system status</b>		
Body temperature	246	0
Body temperature abnormal	46	0
Body temperature decreased	41	0
Body temperature fluctuation	53	0
Body temperature increased	434	0
Body temperature normal	1	0
Breath sounds abnormal	2	0
General physical condition abnormal	1	0
Grip strength	2	0
Grip strength decreased	22	0
Head lag	8	0

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Lymph node palpable	41	0
Male genital examination abnormal	1	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	3	0
Psoriasis area severity index decreased	2	0
Respiratory rate	9	0
Respiratory rate decreased	25	0
Respiratory rate increased	40	0
Skin temperature	42	0
Temperature difference of extremities	10	0
Weight	1	0
Weight abnormal	1	0
Weight decreased	110	0
Weight increased	38	0
<b><i>Pituitary analyses anterior</i></b>		
Blood corticotrophin	1	0
Blood follicle stimulating hormone increased	3	0
Blood growth hormone	3	0
Blood prolactin	3	0
Blood prolactin increased	3	0
Blood thyroid stimulating hormone decreased	1	0
Blood thyroid stimulating hormone increased	8	0
<b><i>Platelet analyses</i></b>		
Mean platelet volume decreased	1	0
Mean platelet volume increased	1	0
Platelet count	3	0
Platelet count abnormal	1	0
Platelet count decreased	73	0
Platelet count increased	6	0
<b><i>Protein analyses NEC</i></b>		
Alpha 1 globulin decreased	1	0
Alpha 2 globulin decreased	1	0
C-reactive protein increased	22	0
<b><i>Red blood cell analyses</i></b>		
Haematocrit	1	0
Haematocrit decreased	1	0
Haematocrit increased	1	0
Haemoglobin decreased	12	0
Haemoglobin increased	2	0
Red blood cell count decreased	1	0
Red blood cell rouleaux formation present	1	0
<b><i>Renal function analyses</i></b>		
Blood creatinine	1	0
Blood creatinine increased	3	0
Glomerular filtration rate decreased	3	0
<b><i>Reproductive hormone analyses</i></b>		
Blood oestrogen decreased	2	0
Blood testosterone decreased	1	0
Blood testosterone increased	1	0

## Case Series Drug Analysis Print

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Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
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
<b><i>Reproductive organ and breast histopathology procedures</i></b>		
Biopsy breast	2	0
Biopsy endometrium	1	0
Smear cervix	2	0
<b><i>Reproductive organ and breast imaging procedures</i></b>		
Breast scan	1	0
Hysteroscopy	2	0
<b><i>Respiratory and pulmonary function diagnostic procedures</i></b>		
Forced expiratory volume increased	2	0
Fractional exhaled nitric oxide normal	1	0
Maximal voluntary ventilation	2	0
Peak expiratory flow rate	1	0
Peak expiratory flow rate decreased	5	0
Pulmonary function test	3	0
Total lung capacity decreased	3	0
Vital capacity	1	0
<b><i>Respiratory tract and thoracic histopathology procedures</i></b>		
Sputum abnormal	3	0
<b><i>Respiratory tract and thoracic imaging procedures</i></b>		
Chest X-ray	19	0
Chest X-ray abnormal	1	0
Chest X-ray normal	2	0
Chest scan	2	0
Computerised tomogram thorax	1	0
<b><i>Skeletal and cardiac muscle analyses</i></b>		
Blood creatine phosphokinase increased	7	0
Muscle enzyme	1	0
Myocardial necrosis marker	1	0
Myocardial necrosis marker increased	3	0
Troponin I increased	2	0
Troponin T increased	1	0
Troponin increased	14	0
<b><i>Therapeutic drug monitoring analyses</i></b>		
Analgesic drug level	8	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
<b><i>Thyroid analyses</i></b>		
Anti-thyroid antibody	1	0
Thyroid function test abnormal	5	0
Thyroxine	1	0
Thyroxine free increased	2	0
Tri-iodothyronine	1	0
Tri-iodothyronine decreased	5	0
<b><i>Tissue enzyme analyses NEC</i></b>		
Blood alkaline phosphatase abnormal	1	0

## Case Series Drug Analysis Print

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Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Blood alkaline phosphatase increased	5	0
Enzyme level increased	1	0
<b>Toxicology laboratory analyses</b>		
Blood caffeine decreased	1	0
Blood lead	1	0
Drug screen positive	2	0
Opiates	1	0
<b>Urinalysis NEC</b>		
Blood urine	15	0
Blood urine present	59	0
Cells in urine	1	0
Glucose urine present	1	0
Protein urine absent	1	0
Protein urine present	1	0
Red blood cells urine	1	0
Urine analysis abnormal	6	0
Urine uric acid increased	1	0
pH urine	6	0
pH urine increased	2	0
<b>Urinary tract function analyses NEC</b>		
Urine output	12	0
Urine output decreased	13	0
Urine output increased	7	0
<b>Urinary tract histopathology procedures</b>		
Urine cytology	1	0
<b>Urinary tract imaging procedures</b>		
Cystoscopy	2	0
Ultrasound kidney normal	1	0
<b>Vascular imaging procedures NEC</b>		
Venogram	2	0
<b>Vascular tests NEC (incl blood pressure)</b>		
Blood pressure abnormal	7	0
Blood pressure ambulatory increased	1	0
Blood pressure decreased	83	0
Blood pressure diastolic	1	0
Blood pressure diastolic decreased	1	0
Blood pressure diastolic increased	4	0
Blood pressure difference of extremities	1	0
Blood pressure increased	248	0
Blood pressure measurement	38	0
Blood pressure normal	2	0
Blood pressure systolic	1	0
Blood pressure systolic decreased	4	0
Blood pressure systolic increased	1	0
<b>Virus identification and serology</b>		
Coronavirus test	11	0
Coronavirus test positive	4	0
Cytomegalovirus 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	10	0
SARS-CoV-2 antibody test negative	15	0

## Case Series Drug Analysis Print

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Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Investigations</b>		
Investigations cont'd		
SARS-CoV-2 antibody test positive	6	0
SARS-CoV-2 test	32	0
SARS-CoV-2 test false negative	2	0
SARS-CoV-2 test false positive	4	0
SARS-CoV-2 test negative	9	0
SARS-CoV-2 test positive	99	0
Viral load	1	0
Viral test	4	0
Viral test positive	1	0
<b>Vitamin analyses</b>		
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
<b>Water and electrolyte analyses NEC</b>		
Urine osmolarity	1	0
Volume blood	1	0
<b>White blood cell analyses</b>		
Eosinophil count	1	0
Eosinophil count decreased	1	0
Eosinophil count increased	3	0
Lymphocyte count	1	0
Lymphocyte count decreased	3	0
Lymphocyte count increased	1	0
Monocyte count increased	1	0
Neutrophil count	3	0
Neutrophil count decreased	9	0
Neutrophil count increased	3	0
White blood cell count	2	0
White blood cell count decreased	11	0
White blood cell count increased	10	0
<b>Investigations SOC TOTAL</b>	<b>5141</b>	<b>3</b>

## Case Series Drug Analysis Print

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Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<b><i>Appetite disorders</i></b>		
Appetite disorder	17	0
Decreased appetite	1224	0
Diet refusal	1	0
Eating disorder symptom	2	0
Food craving	12	0
Food refusal	15	0
Hyperphagia	15	0
Hypophagia	17	0
Increased appetite	32	0
Salt craving	2	0
<b><i>Calcium metabolism disorders</i></b>		
Hypocalcaemia	3	0
Tetany	3	0
<b><i>Diabetes mellitus (incl subtypes)</i></b>		
Diabetes mellitus	50	0
Diabetes mellitus inadequate control	16	1
Increased insulin requirement	2	0
Insulin resistant diabetes	1	0
Latent autoimmune diabetes in adults	2	0
Type 1 diabetes mellitus	16	0
Type 2 diabetes mellitus	4	0
<b><i>Diabetic complications NEC</i></b>		
Diabetic complication	2	0
Diabetic ketoacidosis	12	0
Diabetic ketosis	1	0
<b><i>Disorders of purine metabolism</i></b>		
Gout	94	0
<b><i>Electrolyte imbalance NEC</i></b>		
Electrolyte imbalance	1	0
Fluid imbalance	2	0
<b><i>Fat soluble vitamin deficiencies and disorders</i></b>		
Vitamin D deficiency	7	0
<b><i>Fluid intake decreased</i></b>		
Fluid intake reduced	2	0
<b><i>Fluid intake increased</i></b>		
Polydipsia	6	0
<b><i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i></b>		
Alcohol intolerance	4	0
Breast milk substitute intolerance	1	0
Dairy intolerance	3	0
Food intolerance	17	0
Gluten sensitivity	7	0
Histamine intolerance	4	0
<b><i>General nutritional disorders NEC</i></b>		
Abnormal loss of weight	24	0
Abnormal weight gain	20	0
Cachexia	1	0
Feeding disorder	89	0
Food aversion	8	0
Malnutrition	1	0
Neonatal insufficient breast milk syndrome	3	0
Obesity	1	0



## Case Series Drug Analysis Print

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Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Metabolic disorders</b> Metabolic disorders cont'd		
Overweight	1	0
Poor feeding infant	15	0
Weight loss poor	3	0
<b>Hyperglycaemic conditions NEC</b>		
Glucose tolerance impaired	1	0
Hyperglycaemia	67	0
Insulin resistance	4	0
<b>Hypoglycaemic conditions NEC</b>		
Glycopenia	1	0
Hypoglycaemia	78	0
Hypoglycaemia unawareness	1	0
Postprandial hypoglycaemia	1	0
<b>Iron deficiencies</b>		
Iron deficiency	12	0
<b>Iron excess</b>		
Haemochromatosis	1	0
Iron overload	1	0
<b>Lipid metabolism and deposit disorders NEC</b>		
Body fat disorder	1	0
<b>Magnesium metabolism disorders</b>		
Magnesium deficiency	1	0
<b>Metabolic acidoses (excl diabetic acidoses)</b>		
Ketoacidosis	5	1
Lactic acidosis	2	0
Metabolic acidosis	2	0
<b>Metabolic disorders NEC</b>		
Hypercatabolism	1	0
Metabolic disorder	1	0
<b>Mixed acid-base disorders</b>		
Acidosis	4	0
<b>Potassium imbalance</b>		
Hyperkalaemia	6	0
Hypokalaemia	3	0
Hypokalaemic syndrome	1	0
<b>Sodium imbalance</b>		
Hyponatraemia	10	0
Hyponatraemic syndrome	3	0
Salt intoxication	1	0
<b>Sugar intolerance (excl glucose intolerance)</b>		
Lactose intolerance	2	0
<b>Total fluid volume decreased</b>		
Dehydration	201	0
<b>Total fluid volume increased</b>		
Fluid retention	54	0
Hypervolaemia	5	0
<b>Vitamin deficiencies NEC</b>		
Hypovitaminosis	6	0
<b>Water soluble vitamin deficiencies</b>		
Folate deficiency	5	0
Vitamin B complex deficiency	1	0
Vitamin B12 deficiency	5	0
<b>Metabolic disorders SOC TOTAL</b>	<b>2250</b>	<b>2</b>

## Case Series Drug Analysis Print

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Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<b><i>Arthropathies NEC</i></b>		
Arthritis	305	0
Arthropathy	27	0
Autoimmune arthritis	7	0
Haemarthrosis	5	0
Joint microhaemorrhage	1	0
Palindromic rheumatism	1	0
Polyarthritis	15	0
Rheumatic fever	3	0
Sacroiliitis	5	0
Seronegative arthritis	2	0
<b><i>Bone disorders NEC</i></b>		
Bone cyst	1	0
Exostosis	1	0
Jaw disorder	4	0
Medial tibial stress syndrome	4	0
Osteitis	7	0
Osteonecrosis	1	0
Osteonecrosis of jaw	3	0
Spinal disorder	1	0
<b><i>Bone related signs and symptoms</i></b>		
Bone pain	382	0
Bone swelling	10	0
Coccydynia	3	0
Metatarsalgia	1	0
Pain in jaw	371	0
Pubic pain	2	0
Spinal pain	83	0
<b><i>Bursal disorders</i></b>		
Bursitis	77	0
<b><i>Cartilage disorders</i></b>		
Chondritis	1	0
Costochondritis	99	0
Osteochondritis	1	0
Polychondritis	3	0
<b><i>Connective tissue disorders NEC</i></b>		
Connective tissue disorder	1	0
Polymyalgia rheumatica	62	0
Reynold's syndrome	1	0
Sjogren's syndrome	5	0
Systemic scleroderma	1	0
<b><i>Crystal arthropathic disorders</i></b>		
Chondrocalcinosis pyrophosphate	3	0
Crystal arthropathy	2	0
Gouty arthritis	1	0
<b><i>Epiphyseal disorders</i></b>		
Epiphyses premature fusion	1	0
<b><i>Extremity deformities</i></b>		
Bone deformity	1	0
Finger deformity	2	0
Foot deformity	2	0
Hand deformity	2	0
Knee deformity	1	0

## Case Series Drug Analysis Print

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Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Muscle &amp; tissue disorders cont'd</i>		
Limb deformity	5	0
Musculoskeletal deformity	1	0
<b>Fractures NEC</b>		
Osteoporotic fracture	1	0
<b>Intervertebral disc disorders NEC</b>		
Intervertebral disc protrusion	3	0
<b>Joint related disorders NEC</b>		
Carpal collapse	1	0
Chondromalacia	1	0
Hypermobility syndrome	2	0
Joint deposit	1	0
Joint destruction	1	0
Joint instability	2	0
Joint laxity	3	0
Joint lock	29	0
Patellofemoral pain syndrome	1	0
Periarthritis	187	0
Rotator cuff syndrome	33	0
Temporomandibular joint syndrome	8	0
<b>Joint related signs and symptoms</b>		
Arthralgia	8963	0
Jaw clicking	6	0
Joint effusion	16	0
Joint noise	35	0
Joint range of motion decreased	30	0
Joint stiffness	242	0
Joint swelling	544	0
Joint vibration	3	0
Joint warmth	15	0
Loose body in joint	1	0
<b>Ligament disorders</b>		
Ligament pain	2	0
Ligamentitis	1	0
Symphysiolysis	1	0
<b>Lupus erythematosus (incl subtypes)</b>		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	23	0
<b>Metabolic bone disorders</b>		
Osteopenia	3	0
Osteoporosis	5	0
<b>Muscle infections and inflammations</b>		
Antisynthetase syndrome	3	0
Immune-mediated myositis	1	0
Myositis	39	0
Polymyositis	8	0
<b>Muscle pains</b>		
Fibromyalgia	116	0
Myalgia	10522	0
Myalgia intercostal	2	0
Myofascial pain syndrome	11	0
<b>Muscle related signs and symptoms NEC</b>		
Haematoma muscle	1	0
Muscle atrophy	23	0

## Case Series Drug Analysis Print

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Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Muscle &amp; tissue disorders cont'd</i>		
Muscle discomfort	7	0
Muscle disorder	9	0
Muscle fatigue	345	0
Muscle haemorrhage	1	0
Muscle mass	6	0
Muscle oedema	3	0
Muscle spasms	2037	0
Muscle swelling	38	0
Muscle tightness	86	0
Muscle twitching	470	0
<b><i>Muscle tone abnormalities</i></b>		
Muscle rigidity	16	0
Nuchal rigidity	12	0
Torticollis	6	0
Trismus	36	0
<b><i>Muscle weakness conditions</i></b>		
Muscular weakness	929	0
<b><i>Musculoskeletal and connective tissue conditions NEC</i></b>		
Back disorder	2	0
Chest wall mass	1	0
Growth disorder	2	0
Limb mass	20	0
Mandibular mass	2	0
Mastication disorder	5	0
Mobility decreased	113	0
Muscle contracture	1	0
Musculoskeletal disorder	11	0
Musculoskeletal stiffness	1261	0
Posture abnormal	2	0
Sacroiliac joint dysfunction	1	0
Weight bearing difficulty	4	0
<b><i>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</i></b>		
Facial asymmetry	1	0
Head deformity	2	0
<b><i>Musculoskeletal and connective tissue infections and inflammations NEC</i></b>		
Connective tissue inflammation	1	0
Dactylitis	2	0
Dupuytren's contracture	1	0
Fasciitis	1	0
Plantar fasciitis	13	0
<b><i>Musculoskeletal and connective tissue pain and discomfort</i></b>		
Back pain	2381	0
Flank pain	74	0
Limb discomfort	1474	0
Musculoskeletal chest pain	245	0
Musculoskeletal discomfort	99	0
Musculoskeletal pain	119	0
Neck pain	1884	0
Pain in extremity	12572	2
Rheumatic disorder	14	0
Sacral pain	3	0
<b><i>Myopathies</i></b>		

## Case Series Drug Analysis Print

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Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
Muscle & tissue disorders cont'd		
Mitochondrial myopathy acquired	1	0
Myopathy	6	0
Rhabdomyolysis	12	0
<b>Osteoarthropathies</b>		
Nodal osteoarthritis	1	0
Osteoarthritis	47	0
Spinal osteoarthritis	2	0
<b>Psoriatic arthropathies</b>		
Psoriatic arthropathy	17	0
<b>Rheumatoid arthropathies</b>		
Juvenile idiopathic arthritis	1	0
Rheumatoid arthritis	118	0
Still's disease	2	0
<b>Soft tissue disorders NEC</b>		
Axillary mass	254	0
Fluctuance	1	0
Groin pain	108	0
Neck mass	35	0
Purple glove syndrome	1	0
Soft tissue disorder	3	0
Soft tissue swelling	6	0
<b>Spine and neck deformities</b>		
Kyphosis	2	0
Lordosis	1	0
Neck deformity	1	0
Scoliosis	1	0
Spinal stenosis	2	0
<b>Spondyloarthropathies</b>		
Ankylosing spondylitis	8	0
Arthritis reactive	49	0
Spondylitis	3	0
Spondyloarthropathy	1	0
<b>Synovial disorders</b>		
Synovial cyst	19	0
Synovitis	11	0
<b>Tendon disorders</b>		
Enthesopathy	2	0
Posterior tibial tendon dysfunction	1	0
Tendon disorder	5	0
Tendon pain	20	0
Tendonitis	47	0
Tenosynovitis	4	0
Tenosynovitis stenosaurs	2	0
Trigger finger	28	0
<b>Trunk deformities</b>		
Deformity thorax	1	0
Drooping shoulder syndrome	2	0
Shoulder deformity	2	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>47546</b>	<b>2</b>

## Case Series Drug Analysis Print

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Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<b><i>Angioimmunoblastic T-cell lymphomas</i></b>		
Angioimmunoblastic T-cell lymphoma	1	0
<b><i>B-cell lymphomas NEC</i></b>		
B-cell lymphoma	2	1
Follicular lymphoma	4	0
<b><i>Bone neoplasms malignant (excl sarcomas)</i></b>		
Bone cancer	1	1
<b><i>Bone neoplasms unspecified malignancy</i></b>		
Bone neoplasm	1	0
<b><i>Breast and nipple neoplasms benign</i></b>		
Benign breast neoplasm	1	0
Fibroadenoma of breast	1	0
<b><i>Breast and nipple neoplasms malignant</i></b>		
Breast cancer	37	0
Breast cancer female	1	0
Breast cancer male	2	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
<b><i>Cardiovascular neoplasms benign</i></b>		
Haemangioma	1	0
Pericardial lipoma	1	0
<b><i>Cartilage sarcomas</i></b>		
Chondrosarcoma	1	0
<b><i>Cervix neoplasms malignant</i></b>		
Cervix carcinoma	1	0
<b><i>Colorectal neoplasms malignant</i></b>		
Colon cancer	2	0
Colorectal cancer	1	0
Rectal cancer	2	0
<b><i>Endocrine neoplasms malignant and unspecified NEC</i></b>		
Neuroendocrine tumour	1	0
Thyroid neoplasm	1	0
<b><i>Endometrial neoplasms malignant</i></b>		
Endometrial cancer	1	0
<b><i>Follicular lymphomas</i></b>		
Primary gastrointestinal follicular lymphoma	1	0
<b><i>Gastric neoplasms malignant</i></b>		
Gastric cancer	1	1
<b><i>Gastrointestinal neoplasms malignant NEC</i></b>		
Gastrointestinal carcinoma	3	0
<b><i>Hepatic neoplasms malignant</i></b>		
Hepatocellular carcinoma	1	0
<b><i>Hepatobiliary neoplasms malignancy unspecified</i></b>		
Hepatic neoplasm	1	0
<b><i>Hodgkin's disease NEC</i></b>		
Hodgkin's disease	4	0
<b><i>Islet cell neoplasms and APUDoma NEC</i></b>		
Pancreatic neuroendocrine tumour	1	0
<b><i>Kaposi's sarcomas</i></b>		
Kaposi's sarcoma	1	0
<b><i>Leukaemias NEC</i></b>		

## Case Series Drug Analysis Print

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Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Neoplasms</b> Neoplasms cont'd		
Leukaemia	4	1
<b>Leukaemias acute NEC</b>		
Acute leukaemia	2	0
<b>Leukaemias chronic NEC</b>		
Chronic leukaemia	1	0
<b>Leukaemias chronic lymphocytic</b>		
Chronic lymphocytic leukaemia	3	0
<b>Leukaemias chronic myeloid</b>		
Chronic myeloid leukaemia	1	0
<b>Lip and oral cavity neoplasms malignant</b>		
Lip and/or oral cavity cancer recurrent	1	0
<b>Lymphomas unspecified NEC</b>		
Lymphoma	36	1
<b>Metastases to specified sites</b>		
Metastases to bone	1	0
Metastases to liver	1	0
Metastases to lymph nodes	5	0
<b>Metastases to unknown and unspecified sites</b>		
Metastasis	1	0
<b>Myelodysplastic syndromes</b>		
Myelodysplastic syndrome	3	0
<b>Myeloproliferative disorders (excl leukaemias)</b>		
Essential thrombocythaemia	1	0
<b>Neoplasms malignant site unspecified NEC</b>		
Adenocarcinoma metastatic	1	0
Metastatic neoplasm	2	0
Neoplasm malignant	8	0
Second primary malignancy	1	0
Squamous cell carcinoma	5	0
<b>Neoplasms unspecified malignancy and site unspecified NEC</b>		
Neoplasm	1	0
Neoplasm recurrence	1	0
<b>Nervous system neoplasms benign NEC</b>		
Cranial nerve neoplasm benign	1	0
Neurilemmoma benign	1	0
<b>Nervous system neoplasms unspecified malignancy NEC</b>		
Brain neoplasm	2	0
Meningioma	1	0
Spinal cord neoplasm	1	0
<b>Neuromas</b>		
Acoustic neuroma	2	0
<b>Non-Hodgkin's lymphomas NEC</b>		
Non-Hodgkin's lymphoma	2	0
<b>Ocular neoplasms benign</b>		
Eye naevus	1	0
<b>Oesophageal neoplasms malignant</b>		
Oesophageal cancer metastatic	4	0
<b>Oncologic complications and emergencies</b>		
Cancer pain	1	0
Tumour haemorrhage	1	0
<b>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</b>		
Tonsil cancer	4	0

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Neoplasms</b> <span style="float: right;">Neoplasms cont'd</span>		
<i>Ovarian neoplasms malignant (excl germ cell)</i>		
Ovarian cancer	1	0
<i>Pancreatic neoplasms malignant (excl islet cell and carcinoid)</i>		
Pancreatic carcinoma	4	0
<i>Plasma cell myelomas</i>		
POEMS syndrome	1	0
Plasma cell myeloma	2	0
<i>Plasma cell neoplasms NEC</i>		
TEMPI syndrome	2	0
<i>Prostatic neoplasms malignant</i>		
Prostate cancer	4	0
<i>Renal neoplasms malignant</i>		
Clear cell renal cell carcinoma	1	0
Renal cancer	3	0
<i>Reproductive neoplasms female benign NEC</i>		
Benign hydatidiform mole	2	0
<i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i>		
Bronchial carcinoma	1	0
Lung neoplasm malignant	12	1
<i>Salivary gland neoplasms unspecified malignancy</i>		
Salivary gland neoplasm	1	0
<i>Skin melanomas (excl ocular)</i>		
Malignant melanoma	1	0
<i>Skin neoplasms benign</i>		
Acrochordon	4	0
Anogenital warts	7	0
Fibrous histiocytoma	1	0
Haemangioma of skin	4	0
Melanocytic naevus	6	0
Pyogenic granuloma	1	0
Seborrhoeic keratosis	1	0
Skin papilloma	19	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Basal cell carcinoma	3	0
Bowen's disease	1	0
Neoplasm skin	2	0
Skin cancer	1	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	11	0
<b>Neoplasms SOC TOTAL</b>	<b>292</b>	<b>6</b>



## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i><b>Abnormal reflexes</b></i>		
Areflexia	7	0
Extensor plantar response	2	0
Hoffmann's sign	1	0
Hyperreflexia	4	0
Hyporeflexia	8	0
Reflexes abnormal	3	0
<i><b>Abnormal sleep-related events</b></i>		
Sleep paralysis	25	0
<i><b>Absence seizures</b></i>		
Petit mal epilepsy	27	0
<i><b>Acute polyneuropathies</b></i>		
Acute motor axonal neuropathy	1	0
Acute motor-sensory axonal neuropathy	1	0
Guillain-Barre syndrome	69	2
Miller Fisher syndrome	2	0
Subacute inflammatory demyelinating polyneuropathy	1	0
<i><b>Autonomic nervous system disorders</b></i>		
Anticholinergic syndrome	1	0
Autonomic nervous system imbalance	10	0
Autonomic neuropathy	2	0
Horner's syndrome	2	0
Orthostatic intolerance	2	0
<i><b>Central nervous system aneurysms and dissections</b></i>		
Carotid artery dissection	1	0
Intracranial aneurysm	2	1
<i><b>Central nervous system haemorrhages and cerebrovascular accidents</b></i>		
Brain stem haemorrhage	1	1
Brain stem infarction	1	1
Brain stem stroke	1	0
Carotid artery occlusion	1	0
Carotid artery thrombosis	4	0
Cerebellar artery thrombosis	1	0
Cerebellar haemorrhage	3	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	4	0
Cerebral haemorrhage	48	9
Cerebral infarction	28	2
Cerebral thrombosis	13	0
Cerebrovascular accident	414	17
Embolic stroke	7	0
Haemorrhage intracranial	10	2
Haemorrhagic cerebral infarction	1	0
Haemorrhagic stroke	11	4
Internal capsule infarction	1	0
Intracranial haematoma	1	0
Ischaemic cerebral infarction	1	0
Ischaemic stroke	55	2
Lacunar infarction	4	0

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Lacunar stroke	5	0
Lateral medullary syndrome	1	0
Pseudostroke	1	0
Subarachnoid haemorrhage	14	6
Thalamic infarction	1	0
Thrombotic stroke	4	1
<b>Central nervous system inflammatory disorders NEC</b>		
Arachnoiditis	1	0
Gliosis	1	0
<b>Central nervous system vascular disorders NEC</b>		
Brain hypoxia	4	1
Carotid arteriosclerosis	1	0
Central nervous system vasculitis	1	0
Cerebral amyloid angiopathy	1	0
Cerebral congestion	5	0
Cerebral small vessel ischaemic disease	2	0
Cerebrovascular disorder	2	0
Post cardiac arrest syndrome	1	0
Reversible cerebral vasoconstriction syndrome	1	0
<b>Cerebrovascular venous and sinus thrombosis</b>		
Cerebral venous sinus thrombosis	51	5
Cerebral venous thrombosis	6	0
Superior sagittal sinus thrombosis	6	0
Transverse sinus thrombosis	1	0
<b>Cervical spinal cord and nerve root disorders</b>		
Cervical radiculopathy	1	0
Cervicobrachial syndrome	6	0
<b>Choreiform movements</b>		
Chorea	3	0
<b>Chronic polyneuropathies</b>		
Chronic inflammatory demyelinating polyradiculoneuropathy	2	0
Demyelinating polyneuropathy	1	0
Diabetic neuropathy	1	0
<b>Coma states</b>		
Coma	13	0
Diabetic coma	1	0
Hypoglycaemic coma	1	0
<b>Coordination and balance disturbances</b>		
Ataxia	19	0
Balance disorder	415	0
Cerebellar ataxia	1	0
Coordination abnormal	58	0
Dysdiadochokinesis	1	0
Dysstasia	62	0
Nystagmus	14	0
<b>Cortical dysfunction NEC</b>		
Alexia	2	0
Aphasia	83	0
Apraxia	1	0
Dysgraphia	1	0
Dyslexia	1	0
Dyspraxia	1	0
Neurologic neglect syndrome	1	0

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small>		
Sensory processing disorder	2	0
Visuospatial deficit	1	0
<b>Cranial nerve disorders NEC</b>		
Cranial nerve disorder	2	0
Cranial nerve paralysis	1	0
<b>Dementia (excl Alzheimer's type)</b>		
Dementia	17	0
Dementia with Lewy bodies	1	0
Senile dementia	1	0
<b>Demyelinating disorders NEC</b>		
Acute disseminated encephalomyelitis	6	0
Clinically isolated syndrome	1	0
Demyelination	8	0
Neuromyelitis optica spectrum disorder	2	0
<b>Disturbances in consciousness NEC</b>		
Altered state of consciousness	12	0
Consciousness fluctuating	3	0
Depressed level of consciousness	46	0
Infant sedation	1	0
Lethargy	2240	0
Loss of consciousness	684	1
Postictal state	5	0
Sedation	8	0
Somnolence	1049	0
Stupor	4	0
Syncope	2270	0
<b>Disturbances in sleep phase rhythm</b>		
Circadian rhythm sleep disorder	1	0
Irregular sleep phase	2	0
Irregular sleep wake rhythm disorder	1	0
<b>Dyskinesias and movement disorders NEC</b>		
Akathisia	5	0
Bradykinesia	19	0
Clumsiness	22	0
Dyskinesia	68	0
Extrapyramidal disorder	3	0
Fine motor skill dysfunction	13	0
Foetal movement disorder	4	0
Hyperkinesia	3	0
Hypokinesia	81	0
Motor dysfunction	4	0
Movement disorder	58	0
Psychomotor hyperactivity	26	0
Synkinesis	2	0
Tardive dyskinesia	2	0
<b>Dystonias</b>		
Dystonia	15	0
Writer's cramp	1	0
<b>Encephalitis NEC</b>		
Encephalitis autoimmune	1	0
Limbic encephalitis	1	0
Noninfective encephalitis	5	0
<b>Encephalopathies NEC</b>		

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Autoimmune encephalopathy	1	1
Encephalopathy	5	0
Hashimoto's encephalopathy	1	0
Posterior reversible encephalopathy syndrome	1	0
<b>Eye movement disorders</b>		
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	11	0
<b>Facial cranial nerve disorders</b>		
Bell's palsy	511	0
Facial nerve disorder	9	0
Facial paralysis	394	0
Facial paresis	93	0
Facial spasm	48	0
<b>Generalised tonic-clonic seizures</b>		
Generalised tonic-clonic seizure	62	0
<b>Headaches NEC</b>		
Cervicogenic headache	3	0
Cluster headache	242	0
Cold-stimulus headache	25	0
Drug withdrawal headache	3	0
Exertional headache	8	0
External compression headache	2	0
Headache	26420	0
Medication overuse headache	2	0
New daily persistent headache	8	0
Occipital neuralgia	15	0
Ophthalmoplegic migraine	1	0
Primary cough headache	4	0
Primary headache associated with sexual activity	8	0
Sinus headache	359	0
Tension headache	565	0
Thunderclap headache	14	0
Vascular headache	17	0
<b>Hydrocephalic conditions</b>		
Hydrocephalus	3	0
<b>Hypoglossal nerve disorders</b>		
Tongue paralysis	1	0
<b>Increased intracranial pressure disorders</b>		
Brain compression	2	0
Brain oedema	8	2
Idiopathic intracranial hypertension	9	0
Intracranial pressure increased	3	0
<b>Intellectual disabilities</b>		
Intellectual disability	3	0
<b>Lumbar spinal cord and nerve root disorders</b>		
Sciatica	102	0
<b>Memory loss (excl dementia)</b>		
Amnesia	192	0
Memory impairment	207	0

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Transient global amnesia	9	0
<b><i>Mental impairment (excl dementia and memory loss)</i></b>		
Cognitive disorder	88	0
Cognitive linguistic deficit	1	0
Disturbance in attention	328	0
Mental impairment	49	0
<b><i>Migraine headaches</i></b>		
Basilar migraine	1	0
Hemiplegic migraine	30	0
Migraine	3013	0
Migraine with aura	195	0
Migraine without aura	19	0
Ophthalmic migraine	5	0
Retinal migraine	34	0
Typical aura without headache	8	0
Vestibular migraine	19	0
<b><i>Mixed cranial nerve disorders</i></b>		
Bulbar palsy	2	0
<b><i>Mononeuropathies</i></b>		
Carpal tunnel syndrome	23	0
Cubital tunnel syndrome	3	0
Meralgia paraesthetica	2	0
Mononeuritis	2	0
Mononeuropathy	4	0
Nerve compression	25	0
Peripheral nerve lesion	2	0
Peroneal nerve palsy	17	0
Piriformis syndrome	1	0
Pudendal canal syndrome	2	0
Sciatic nerve neuropathy	2	0
Ulnar nerve palsy	2	0
Ulnar neuritis	3	0
Ulnar tunnel syndrome	2	0
<b><i>Motor neurone diseases</i></b>		
Lower motor neurone lesion	1	0
Motor neurone disease	2	1
<b><i>Multiple sclerosis acute and progressive</i></b>		
Band sensation	1	0
Multiple sclerosis	35	0
Multiple sclerosis relapse	25	0
Tumefactive multiple sclerosis	1	1
<b><i>Muscle tone abnormal</i></b>		
Drop attacks	2	0
Hypertonia	2	0
Hypotonia	32	0
Morvan syndrome	1	0
Muscle tone disorder	1	0
Serotonin syndrome	1	0
Stiff leg syndrome	1	0
<b><i>Myelitis (incl infective)</i></b>		
Myelitis transverse	27	0
<b><i>Narcolepsy and hypersomnia</i></b>		
Cataplexy	3	0

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Hypersomnia	114	0
Narcolepsy	5	0
<b><i>Nervous system disorders NEC</i></b>		
Central nervous system lesion	2	0
Cerebral disorder	1	0
Nervous system disorder	16	0
Neurotoxicity	4	0
Psychomotor skills impaired	1	0
<b><i>Neurologic visual problems NEC</i></b>		
Hemianopia	1	0
Hemianopia homonymous	2	0
Quadrantanopia	1	0
Tunnel vision	19	0
<b><i>Neurological signs and symptoms NEC</i></b>		
Agitation neonatal	1	0
Clonus	5	0
Decerebrate posture	1	0
Decorticate posture	1	0
Dizziness	9907	0
Dizziness exertional	45	0
Dizziness postural	747	0
Drooling	22	0
Fontanelle bulging	2	0
Head discomfort	343	0
Hyporesponsive to stimuli	2	0
Inability to crawl	3	0
Infant irritability	10	0
Meningism	2	0
Myoclonus	29	0
Neurological symptom	49	0
Patient elopement	1	0
Persistent postural-perceptual dizziness	17	0
Presyncope	638	0
Sensory overload	4	0
Slow response to stimuli	4	0
Tongue biting	8	0
Unresponsive to stimuli	53	0
<b><i>Neuromuscular disorders NEC</i></b>		
Muscle contractions involuntary	26	0
Muscle spasticity	13	0
Neuromuscular pain	3	0
<b><i>Neuromuscular junction dysfunction</i></b>		
Myasthenia gravis	8	0
Myasthenia gravis crisis	2	0
<b><i>Olfactory nerve disorders</i></b>		
Anosmia	279	0
Hyposmia	16	0
Parosmia	261	0
<b><i>Optic nerve disorders NEC</i></b>		
Optic neuritis	28	0
<b><i>Paraesthesias and dysaesthesias</i></b>		
Burning feet syndrome	8	0
Burning sensation	555	0

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Burning sensation mucosal	2	0
Dysaesthesia	7	0
Formication	41	0
Hand-arm vibration syndrome	3	0
Hemianaesthesia	2	0
Hemiparaesthesia	5	0
Hyperaesthesia	104	0
Hypoaesthesia	2953	0
Lhermitte's sign	1	0
Paraesthesia	4103	0
Reversed hot-cold sensation	4	0
Synaesthesia	1	0
<b><i>Paralysis and paresis (excl cranial nerve)</i></b>		
Diplegia	16	0
Hemiparesis	52	0
Hemiplegia	42	0
Locked-in syndrome	1	0
Monoparesis	70	0
Monoplegia	86	0
Paralysis	130	0
Paraparesis	3	0
Paraplegia	3	0
Paresis	6	0
Quadriparesis	1	0
Quadriplegia	1	0
<b><i>Parkinson's disease and parkinsonism</i></b>		
Freezing phenomenon	14	0
Hypokinetic dysarthria	1	0
Parkinson's disease	4	0
Parkinsonian gait	1	0
Parkinsonian rest tremor	1	0
Parkinsonism	4	0
Reduced facial expression	10	0
<b><i>Partial complex seizures</i></b>		
Dreamy state	6	0
Focal dyscognitive seizures	4	0
Temporal lobe epilepsy	2	0
<b><i>Partial simple seizures NEC</i></b>		
Autonomic seizure	1	0
<b><i>Peripheral neuropathies NEC</i></b>		
Axonal neuropathy	2	0
Neuralgic amyotrophy	4	0
Neuritis	7	0
Neuropathy peripheral	124	0
Peripheral sensorimotor neuropathy	1	0
Peripheral sensory neuropathy	12	0
Polyneuropathy	3	0
Thoracic outlet syndrome	2	0
<b><i>Seizures and seizure disorders NEC</i></b>		
Atonic seizures	6	0
Change in seizure presentation	2	0
Clonic convulsion	3	0
Convulsions local	1	0

## Case Series Drug Analysis Print

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Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Epilepsy	159	0
Epileptic aura	2	0
Epileptic encephalopathy	1	0
Febrile convulsion	17	0
Idiopathic generalised epilepsy	1	0
Partial seizures	22	0
Post stroke seizure	1	0
Psychogenic seizure	10	0
Seizure	630	0
Seizure anoxic	2	0
Seizure cluster	6	0
Seizure like phenomena	3	0
Status epilepticus	38	0
Tonic clonic movements	4	0
Tonic convulsion	29	0
Tonic posturing	1	0
<b>Sensory abnormalities NEC</b>		
Ageusia	533	0
Allodynia	26	0
Aura	24	0
Complex regional pain syndrome	5	0
Dysgeusia	1180	0
Electric shock sensation	41	0
Hypergeusia	1	0
Hypogeusia	7	0
Intercostal neuralgia	1	0
Loss of proprioception	3	0
Morton's neuralgia	1	0
Neuralgia	558	0
Persistent genital arousal disorder	2	0
Phantom limb syndrome	5	0
Post herpetic neuralgia	15	0
Restless arm syndrome	2	0
Restless legs syndrome	141	0
Sensory disturbance	109	0
Sensory loss	85	0
Taste disorder	266	0
Visual perseveration	3	0
<b>Sleep disturbances NEC</b>		
Microsleep	1	0
Sleep deficit	10	0
Sudden onset of sleep	1	0
<b>Speech and language abnormalities</b>		
Dysarthria	201	0
Incoherent	14	0
Language disorder	2	0
Repetitive speech	3	0
Slow speech	19	0
Speech disorder	73	0
Speech disorder developmental	1	0
<b>Spinal cord and nerve root disorders NEC</b>		
Myelopathy	1	0
Radiculitis brachial	14	0



## Case Series Drug Analysis Print

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Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
Nervous system disorders cont'd		
Radiculopathy	8	0
<b>Structural brain disorders NEC</b>		
Brain injury	8	2
Cerebral ventricle dilatation	1	0
Hyperintensity in brain deep nuclei	1	0
<b>Transient cerebrovascular events</b>		
Transient ischaemic attack	154	3
<b>Tremor (excl congenital)</b>		
Essential tremor	5	0
Head titubation	13	0
Resting tremor	4	0
Tremor	1825	0
<b>Trigeminal disorders</b>		
Numb chin syndrome	2	0
Trigeminal nerve disorder	3	0
Trigeminal neuralgia	66	0
Trigeminal neuritis	3	0
<b>Vagus nerve disorders</b>		
Vocal cord paralysis	2	0
<b>Vertigos NEC</b>		
Cervicogenic vertigo	1	0
Vertigo CNS origin	3	0
<b>Nervous system disorders SOC TOTAL</b>	<b>69181</b>	<b>67</b>

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i><b>Abortion related conditions and complications</b></i>		
Anembryonic gestation	2	0
<i><b>Abortions not specified as induced or spontaneous</b></i>		
Abortion	1	0
Abortion missed	5	0
<i><b>Abortions spontaneous</b></i>		
Abortion spontaneous	390	0
Abortion threatened	2	0
<i><b>Amniotic fluid and cavity disorders of pregnancy NEC</b></i>		
Amniorrhoea	2	0
<i><b>Foetal complications NEC</b></i>		
Foetal cardiac disorder	1	0
Foetal distress syndrome	1	0
Foetal hypokinesia	14	0
<i><b>Foetal growth complications</b></i>		
Foetal growth restriction	5	0
<i><b>Gestational age and weight conditions</b></i>		
Low birth weight baby	1	0
Premature baby	5	1
<i><b>Haemorrhagic complications of pregnancy</b></i>		
Haemorrhage in pregnancy	3	0
Premature separation of placenta	3	0
Subchorionic haematoma	2	0
Subchorionic haemorrhage	1	0
<i><b>Hypertension associated disorders of pregnancy</b></i>		
Pre-eclampsia	1	0
<i><b>Labour onset and length abnormalities</b></i>		
Induced labour	1	0
Premature delivery	1	0
Premature labour	7	0
Premature rupture of membranes	3	0
Threatened labour	1	0
<i><b>Maternal complications of delivery NEC</b></i>		
Retained placenta or membranes	2	0
<i><b>Maternal complications of labour NEC</b></i>		
Uterine contractions abnormal	1	0
Uterine hypertonus	9	0
<i><b>Maternal complications of pregnancy NEC</b></i>		
Biochemical pregnancy	1	0
Complication of pregnancy	1	0
Decidual cast	4	0
Ectopic pregnancy	10	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><b>Normal newborn status</b></i>		
Normal newborn	1	0
<i><b>Normal pregnancy, labour and delivery</b></i>		
Labour pain	1	0
Live birth	7	0
Pregnancy	32	0

## Case Series Drug Analysis Print

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Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Pregnancy conditions</b> <small>Pregnancy conditions cont'd</small>		
Uterine contractions during pregnancy	6	0
<b>Placental abnormalities (excl neoplasms)</b>		
Foetal vascular malperfusion	2	0
Placental disorder	1	0
Placental insufficiency	1	0
Small size placenta	1	0
<b>Postpartum complications NEC</b>		
Postpartum haemorrhage	4	0
<b>Pregnancy complicated by maternal disorders</b>		
Gestational diabetes	2	0
Peripartum cardiomyopathy	1	0
<b>Stillbirth and foetal death</b>		
Foetal death	4	2
Stillbirth	8	7
<b>Unintended pregnancies</b>		
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
<b>Pregnancy conditions SOC TOTAL</b>	<b>585</b>	<b>10</b>

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b><i>Device electrical issues</i></b>		
Electromagnetic interference	1	0
<b><i>Device issues NEC</i></b>		
Device connection issue	1	0
Device failure	1	0
Device issue	2	0
<b><i>Device malfunction events NEC</i></b>		
Device infusion issue	1	0
Device malfunction	1	0
Device pacing issue	1	0
Device stimulation issue	1	0
Oversensing	17	0
Thrombosis in device	11	0
Undersensing	1	0
<b><i>Device physical property and chemical issues</i></b>		
Device breakage	1	0
Device defective	9	0
Device kink	1	0
Needle issue	3	0
<b><i>Product contamination and sterility issues</i></b>		
Product contamination	12	0
Product contamination physical	6	0
<b><i>Product packaging issues</i></b>		
Packaging design issue	1	0
Product closure issue	1	0
<b><i>Product physical issues</i></b>		
Liquid product physical issue	10	0
Product after taste	2	0
Product deposit	1	0
Product odour abnormal	3	0
Product physical issue	2	0
Product taste abnormal	9	0
<b><i>Product quality issues NEC</i></b>		
Product complaint	1	0
Product origin unknown	5	0
<b><i>Product supply and availability issues</i></b>		
Product availability issue	1	0
<b>null SOC TOTAL</b>	<b>106</b>	<b>0</b>

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	28	0
Behaviour disorder	2	0
Breath holding	6	0
Staring	7	0
<b><i>Adjustment disorders</i></b>		
Adjustment disorder	1	0
Adjustment disorder with depressed mood	4	0
<b><i>Affect alterations NEC</i></b>		
Affect lability	14	0
Constricted affect	3	0
Flat affect	11	0
Inappropriate affect	22	0
<b><i>Amnesic symptoms</i></b>		
Paramnesia	7	0
<b><i>Anxiety disorders NEC</i></b>		
Anxiety disorder	1	0
Generalised anxiety disorder	1	0
Neurosis	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	82	0
Anxiety	892	0
Immunisation anxiety related reaction	3	0
Nervousness	185	0
Stress	108	0
Tension	39	0
<b><i>Attention deficit and disruptive behaviour disorders</i></b>		
Attention deficit hyperactivity disorder	7	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Aggression	15	0
Attention-seeking behaviour	1	0
Aversion	1	0
Disinhibition	2	0
Indifference	6	0
Paranoia	25	0
Personality change	4	0
Social avoidant behaviour	5	0
Soliloquy	2	0
Suspiciousness	1	0
<b><i>Bipolar disorders</i></b>		
Bipolar I disorder	2	0
Bipolar disorder	4	0
<b><i>Cognitive and attention disorders and disturbances NEC</i></b>		
Daydreaming	8	0
Distractibility	1	0
Mental fatigue	212	0
<b><i>Communications disorders</i></b>		
Communication disorder	5	0
Mutism	3	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	923	0
Disorientation	298	0
<b><i>Decreased physical activity levels</i></b>		

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Catatonia	1	0
<b>Deliria</b>		
Delirium	129	0
<b>Delusional symptoms</b>		
Delusion	14	0
<b>Depressive disorders</b>		
Agitated depression	6	0
Depression	350	0
Depression suicidal	15	0
Major depression	12	0
Mixed anxiety and depressive disorder	3	0
<b>Dissociative states</b>		
Depersonalisation/derealisation disorder	11	0
Dissociation	31	0
Dissociative amnesia	3	0
Dissociative disorder	2	0
<b>Disturbances in initiating and maintaining sleep</b>		
Initial insomnia	23	0
Insomnia	1551	0
Middle insomnia	32	0
Terminal insomnia	31	0
<b>Dyssomnias</b>		
Breathing-related sleep disorder	1	0
Dyssomnia	1	0
Poor quality sleep	227	0
<b>Eating disorders NEC</b>		
Bulimia nervosa	1	0
Eating disorder	12	0
Selective eating disorder	1	0
<b>Emotional and mood disturbances NEC</b>		
Anger	38	0
Dysphoria	2	0
Emotional disorder	58	0
Emotional distress	46	0
Emotional poverty	1	0
Euphoric mood	45	0
Frustration tolerance decreased	2	0
Irritability	206	0
Mood altered	57	0
<b>Factitious disorders</b>		
Factitious disorder	4	0
<b>Fear symptoms and phobic disorders (incl social phobia)</b>		
Agoraphobia	2	0
Fear	21	0
Fear of death	1	0
Fear of eating	1	0
Fear of falling	3	0
Fear of injection	6	0
Osmophobia	1	0
Phobia	3	0
Phonophobia	3	0
Social anxiety disorder	2	0
Social fear	1	0

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
<i><b>Fluctuating mood symptoms</b></i>		
Mood swings	143	0
<i><b>Hallucinations (excl sleep-related)</b></i>		
Hallucination	217	0
Hallucination, auditory	18	0
Hallucination, olfactory	15	0
Hallucination, tactile	1	0
Hallucination, visual	28	0
Hallucinations, mixed	3	0
<i><b>Increased physical activity levels</b></i>		
Restlessness	154	0
<i><b>Infancy, childhood and adolescence psychiatric disorders NEC</b></i>		
Social (pragmatic) communication disorder	1	0
<i><b>Learning disorders</b></i>		
Learning disability	1	0
Learning disorder	1	0
<i><b>Mental disorders NEC</b></i>		
Mental disorder	16	0
Mental status changes	1	0
Psychological factor affecting medical condition	1	0
<i><b>Mood alterations with depressive symptoms</b></i>		
Anhedonia	3	0
Decreased interest	9	0
Depressed mood	402	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	42	0
<i><b>Mood alterations with manic symptoms</b></i>		
Hypomania	2	0
Mania	11	0
<i><b>Mood disorders NEC</b></i>		
Affective disorder	3	0
Apathy	34	0
Boredom	1	0
Laziness	3	0
Listless	22	0
Mood disorder due to a general medical condition	1	0
<i><b>Narcolepsy and associated conditions</b></i>		
Hypnagogic hallucination	4	0
Hypnopompic hallucination	2	0
Sleep attacks	3	0
<i><b>Obsessive-compulsive disorders and symptoms</b></i>		
Obsessive-compulsive symptom	1	0
<i><b>Orgasmic disorders and disturbances</b></i>		
Anorgasmia	5	0
Female orgasmic disorder	2	0
Orgasm abnormal	4	0
Orgasmic sensation decreased	1	0

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Premature ejaculation	1	0
<b>Panic attacks and disorders</b>		
Panic attack	204	0
Panic disorder	5	0
Panic reaction	28	0
<b>Paraphilias and paraphilic disorders</b>		
Transvestism	1	0
<b>Parasomnias</b>		
Abnormal dreams	193	0
Abnormal sleep-related event	1	0
Confusional arousal	1	0
Exploding head syndrome	2	0
Nightmare	204	0
Parasomnia	4	0
Sleep inertia	1	0
Sleep talking	6	0
Sleep terror	26	0
Somnambulism	7	0
<b>Perception disturbances NEC</b>		
Autoscopy	17	0
Deja vu	2	0
Derealisation	9	0
Flashback	4	0
Illusion	4	0
Near death experience	1	0
Time perception altered	2	0
<b>Personality disorders NEC</b>		
Personality disorder	1	0
Self esteem decreased	1	0
<b>Pervasive developmental disorders NEC</b>		
Autism spectrum disorder	3	0
<b>Psychiatric elimination disorders</b>		
Enuresis	28	0
<b>Psychiatric symptoms NEC</b>		
Helplessness	1	0
Hypervigilance	9	0
Psychiatric symptom	5	0
Psychological trauma	4	0
Trance	1	0
<b>Psychotic disorder NEC</b>		
Acute psychosis	1	0
Psychotic behaviour	1	0
Psychotic disorder	25	0
<b>Schizophrenia NEC</b>		
Schizophrenia	1	0
<b>Sexual and gender identity disorders NEC</b>		
Gender dysphoria	1	0
<b>Sexual arousal disorders</b>		
Disturbance in sexual arousal	3	0
Sexual inhibition	1	0
<b>Sexual desire disorders</b>		
Hypersexuality	1	0
Libido decreased	18	0



## Case Series Drug Analysis Print

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Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Libido increased	7	0
Loss of libido	18	0
<b><i>Sexual dysfunction NEC</i></b>		
Genito-pelvic pain/penetration disorder	1	0
<b><i>Sleep disorders NEC</i></b>		
Sleep disorder	228	0
Sleep disorder due to general medical condition, insomnia type	5	0
<b><i>Somatic symptom disorders</i></b>		
Conversion disorder	22	0
Habit cough	21	0
Somatic symptom disorder	2	0
Vomiting psychogenic	1	0
<b><i>Speech and language usage disturbances</i></b>		
Disorganised speech	7	0
Logorrhoea	2	0
<b><i>Speech articulation and rhythm disturbances</i></b>		
Dysphemia	24	0
Lack of spontaneous speech	1	0
Pressure of speech	1	0
<b><i>Stereotypies and automatisms</i></b>		
Automatism	1	0
Bruxism	13	0
Head banging	11	0
Stereotypy	1	0
<b><i>Stress disorders</i></b>		
Burnout syndrome	2	0
Post-traumatic stress disorder	4	0
<b><i>Substance related and addictive disorders</i></b>		
Alcohol problem	1	0
Alcoholic hangover	1	0
Alcoholism	5	0
Nicotine dependence	2	0
<b><i>Suicidal and self-injurious behaviour</i></b>		
Completed suicide	1	1
Intentional self-injury	6	0
Self-injurious ideation	2	0
Suicidal ideation	41	0
Suicide attempt	8	0
Suicide threat	1	0
<b><i>Thinking disturbances</i></b>		
Bradyphrenia	40	0
Flight of ideas	1	0
Intrusive thoughts	7	0
Morbid thoughts	1	0
Tachyphrenia	7	0
Thinking abnormal	19	0
Thought blocking	1	0
<b><i>Tic disorders</i></b>		
Tic	14	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>8430</b>	<b>1</b>

## Case Series Drug Analysis Print

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Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i><b>Bladder and urethral symptoms</b></i>		
Bladder discomfort	3	0
Bladder irritation	8	0
Bladder pain	30	0
Dysuria	51	0
Incontinence	35	0
Lower urinary tract symptoms	3	0
Micturition disorder	2	0
Micturition urgency	44	0
Pollakiuria	141	0
Stress urinary incontinence	1	0
Urethral pain	7	0
Urge incontinence	3	0
Urinary hesitation	2	0
Urinary incontinence	63	0
Urinary retention	44	0
Urine flow decreased	18	0
<i><b>Bladder disorders NEC</b></i>		
Bladder disorder	9	0
Bladder fibrosis	1	0
Bladder prolapse	1	0
Urinary bladder haemorrhage	3	0
<i><b>Bladder infections and inflammations</b></i>		
Cystitis interstitial	5	0
Cystitis noninfective	1	0
<i><b>Genital and urinary tract disorders NEC</b></i>		
Genitourinary symptom	2	0
Urinary tract disorder	4	0
<i><b>Glomerulonephritis and nephrotic syndrome</b></i>		
Glomerulonephritis minimal lesion	5	0
Glomerulonephritis rapidly progressive	2	0
IgA nephropathy	4	0
Nephrotic syndrome	18	0
<i><b>Myoneurogenic bladder disorders</b></i>		
Bladder dysfunction	5	0
Hypertonic bladder	3	0
Hypotonic urinary bladder	1	0
Loss of bladder sensation	3	0
Neurogenic bladder	2	0
<i><b>Nephritis NEC</b></i>		
Lupus nephritis	1	0
Nephritis	2	0
Tubulointerstitial nephritis	2	0
<i><b>Nephropathies and tubular disorders NEC</b></i>		
Nephropathy	1	0
<i><b>Renal disorders NEC</b></i>		
Renal disorder	6	1
Renal haemorrhage	1	0
Renal mass	1	0
<i><b>Renal failure and impairment</b></i>		
Acute kidney injury	47	4
Anuria	3	0
Chronic kidney disease	4	0

## Case Series Drug Analysis Print

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Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
Renal & urinary disorders cont'd		
Oliguria	1	0
Renal failure	23	1
Renal impairment	25	0
Renal injury	2	0
<b>Renal lithiasis</b>		
Nephrolithiasis	10	0
<b>Renal neoplasms</b>		
Renal cyst	1	0
<b>Renal obstructive disorders</b>		
Hydronephrosis	2	0
<b>Renal structural abnormalities and trauma</b>		
Kidney small	2	0
<b>Renal vascular and ischaemic conditions</b>		
Renal aneurysm	1	0
Renal infarct	2	0
Renal tubular necrosis	2	0
Renal vasculitis	1	1
<b>Structural and obstructive urethral disorders (excl congenital)</b>		
Urethral stenosis	1	0
<b>Ureteric disorders NEC</b>		
Ureteric stenosis	1	0
<b>Urinary abnormalities</b>		
Albuminuria	1	0
Chromaturia	57	0
Haematuria	41	0
Ketonuria	1	0
Myoglobinuria	1	0
Proteinuria	12	0
Urine abnormality	11	0
Urine odour abnormal	9	0
<b>Urinary tract lithiasis (excl renal)</b>		
Calculus urinary	1	0
<b>Urinary tract signs and symptoms NEC</b>		
Costovertebral angle tenderness	1	0
Cystitis-like symptom	1	0
Haemorrhage urinary tract	24	1
Nocturia	3	0
Polyuria	9	0
Renal colic	4	0
Renal pain	300	0
Urinary tract discomfort	1	0
Urinary tract pain	6	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>1149</b>	<b>8</b>

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Benign and malignant breast neoplasms</b></i>		
Breast cyst	14	0
<i><b>Breast disorders NEC</b></i>		
Breast disorder	1	0
Breast enlargement	26	0
Breast mass	123	0
Gynaecomastia	4	0
Mastoptosis	1	0
Nipple disorder	1	0
<i><b>Breast infections and inflammations</b></i>		
Breast inflammation	4	0
Nipple inflammation	2	0
<i><b>Breast signs and symptoms</b></i>		
Breast discharge	4	0
Breast discomfort	11	0
Breast engorgement	11	0
Breast haematoma	1	0
Breast oedema	5	0
Breast pain	678	0
Breast swelling	148	0
Breast tenderness	84	0
Nipple pain	38	1
Nipple swelling	4	0
<i><b>Cervix disorders NEC</b></i>		
Cervical dysplasia	2	0
Cervix disorder	1	0
Cervix haemorrhage uterine	5	0
Ectropion of cervix	4	0
<i><b>Cervix infections and inflammations</b></i>		
Cervix inflammation	1	0
<i><b>Cervix neoplasms</b></i>		
Cervical polyp	1	0
<i><b>Erection and ejaculation conditions and disorders</b></i>		
Ejaculation disorder	2	0
Ejaculation failure	3	0
Erectile dysfunction	66	0
Erection increased	3	0
Organic erectile dysfunction	16	0
Painful ejaculation	1	0
Spontaneous ejaculation	1	0
Spontaneous penile erection	2	0
<i><b>Fallopian tube and ovary infections and inflammations</b></i>		
Noninfective oophoritis	4	0
<i><b>Lactation disorders</b></i>		
Breast milk discolouration	3	0
Breast milk odour abnormal	2	0
Galactorrhoea	5	0
Galactostasis	1	0
Lactation disorder	9	0
Lactation puerperal increased	5	0
Suppressed lactation	46	0
<i><b>Menopausal effects NEC</b></i>		
Artificial menopause	1	0

## Case Series Drug Analysis Print

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Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Reproductive &amp; breast disorders cont'd</i>		
Menopausal disorder	1	0
Menopausal symptoms	31	0
Menopause delayed	1	0
Premature menopause	18	0
<b><i>Menopausal effects on the genitourinary tract</i></b>		
Atrophic vulvovaginitis	2	0
Postmenopausal haemorrhage	98	0
<b><i>Menstruation and uterine bleeding NEC</i></b>		
Abnormal uterine bleeding	6	0
Abnormal withdrawal bleeding	1	0
Bleeding anovulatory	1	0
Dysmenorrhoea	2762	0
Intermenstrual bleeding	1071	0
Menstrual discomfort	28	0
Menstrual disorder	1810	0
Menstruation irregular	3203	0
Premenstrual dysphoric disorder	11	0
Premenstrual headache	10	0
Premenstrual pain	116	0
Premenstrual syndrome	105	0
Retrograde menstruation	1	0
Withdrawal bleed	15	0
<b><i>Menstruation with decreased bleeding</i></b>		
Amenorrhoea	584	0
Hypomenorrhoea	640	0
Menstruation delayed	4756	0
Oligomenorrhoea	157	0
<b><i>Menstruation with increased bleeding</i></b>		
Heavy menstrual bleeding	5261	0
Menometrorrhagia	17	0
Polymenorrhoea	831	0
<b><i>Ovarian and fallopian tube cysts and neoplasms</i></b>		
Haemorrhagic ovarian cyst	1	0
Ovarian cyst	25	0
Ovarian cyst ruptured	1	0
Polycystic ovaries	47	0
<b><i>Ovarian and fallopian tube disorders NEC</i></b>		
Adnexal torsion	1	0
Hydrosalpinx	2	0
Ovarian enlargement	1	0
Ovarian haemorrhage	6	0
Ovulation disorder	2	0
Ovulation pain	65	0
Premature ovulation	4	0
<b><i>Pelvic prolapse conditions</i></b>		
Vaginal prolapse	1	0
<b><i>Pelvis and broad ligament disorders NEC</i></b>		
Adnexa uteri mass	1	0
Adnexa uteri pain	48	0
Pelvic congestion	1	0
Pelvic floor muscle weakness	1	0
Pelvic haemorrhage	20	0
<b><i>Penile and scrotal infections and inflammations</i></b>		

## Case Series Drug Analysis Print

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Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Reproductive &amp; breast disorders cont'd</i>		
Balanoposthitis	3	0
<b><i>Penile disorders NEC (excl erection and ejaculation)</i></b>		
Penile blister	1	0
Penile discharge	1	0
Penile discomfort	1	0
Penile erythema	1	0
Penile haemorrhage	3	0
Penile oedema	1	0
Penile pain	1	0
Penile size reduced	1	0
Penile swelling	5	0
Penis disorder	10	0
<b><i>Prostate and seminal vesicles infections and inflammations</i></b>		
Prostatitis	3	0
<b><i>Prostatic neoplasms and hypertrophy</i></b>		
Benign prostatic hyperplasia	2	0
<b><i>Prostatic signs, symptoms and disorders NEC</i></b>		
Prostatic pain	1	0
Prostatomegaly	3	0
<b><i>Reproductive tract disorders NEC (excl neoplasms)</i></b>		
Genital erosion	1	0
Genital haemorrhage	24	0
Genital hypoaesthesia	1	0
Genital lesion	2	0
Genital paraesthesia	1	0
Genital ulceration	6	0
Perineal ulceration	1	0
<b><i>Reproductive tract infections and inflammations NEC</i></b>		
Genital tract inflammation	1	0
<b><i>Reproductive tract signs and symptoms NEC</i></b>		
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	105	0
Perineal pain	2	0
Perineal rash	1	0
Pruritus genital	4	0
<b><i>Scrotal disorders NEC</i></b>		
Acquired hydrocele	1	0
Scrotal angiokeratoma	1	0
Scrotal discomfort	1	0
Scrotal erythema	2	0
Scrotal exfoliation	2	0
Scrotal pain	21	0
Scrotal swelling	4	0
Scrotum erosion	1	0
Varicocele	2	0
<b><i>Sexual function and fertility disorders NEC</i></b>		
Dyspareunia	6	0
Infertility	11	0

## Case Series Drug Analysis Print

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Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Reproductive &amp; breast disorders cont'd</i>		
Infertility female	3	0
Sexual dysfunction	8	0
<b><i>Spermatogenesis and semen disorders</i></b>		
Aspermia	1	0
Haemospermia	6	0
Semen discolouration	1	0
<b><i>Testicular and epididymal disorders NEC</i></b>		
Testicular disorder	4	0
Testicular oedema	1	0
Testicular pain	60	0
Testicular swelling	10	0
Testicular torsion	1	0
Testis discomfort	3	0
<b><i>Uterine disorders NEC</i></b>		
Adenomyosis	7	0
Endometrial thickening	4	0
Endometriosis	85	0
Uterine haemorrhage	37	0
Uterine pain	14	0
<b><i>Uterine infections and inflammations (excl cervix)</i></b>		
Uterine inflammation	1	0
<b><i>Uterine neoplasms</i></b>		
Uterine polyp	4	0
<b><i>Uterine tone disorders</i></b>		
Uterine spasm	29	0
<b><i>Vulvovaginal cysts and neoplasms</i></b>		
Bartholin's cyst	1	0
Vaginal cyst	7	0
Vaginal polyp	1	0
<b><i>Vulvovaginal disorders NEC</i></b>		
Vaginal haemorrhage	1503	0
Vaginal mucosal blistering	1	0
Vaginal ulceration	2	0
Vulval disorder	1	0
Vulval haemorrhage	27	0
Vulval ulceration	7	0
Vulvovaginal ulceration	4	0
<b><i>Vulvovaginal signs and symptoms</i></b>		
Clitoral engorgement	1	0
Coital bleeding	6	0
Labia enlarged	1	0
Vaginal discharge	76	0
Vaginal lesion	1	0
Vaginal odour	2	0
Vulval oedema	2	0
Vulvovaginal burning sensation	5	0
Vulvovaginal discomfort	1	0
Vulvovaginal dryness	5	0
Vulvovaginal erythema	1	0
Vulvovaginal pain	26	0
Vulvovaginal pruritus	10	0
Vulvovaginal rash	2	0
Vulvovaginal swelling	4	0

# Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Reproductive & breast disorders		
Reproductive & breast disorders cont'd		
Reproductive & breast disorders SOC TOTAL	25342	1



## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Apnoea	6	0
Apnoeic attack	1	0
Dyspnoea	5042	5
Dyspnoea at rest	11	0
Dyspnoea exertional	36	1
Grunting	1	0
Hyperventilation	50	0
Hypopnoea	114	0
Hypoventilation	1	0
Irregular breathing	22	0
Mouth breathing	6	0
Nocturnal dyspnoea	2	0
Orthopnoea	3	0
Respiration abnormal	59	0
Respiratory arrest	16	0
Respiratory depression	1	0
Respiratory distress	19	0
Sleep apnoea syndrome	13	0
Tachypnoea	27	0
<i><b>Bronchial conditions NEC</b></i>		
Bronchial secretion retention	4	0
Bronchiectasis	14	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	356	0
Asthma late onset	3	0
Bronchospasm	17	0
Chronic obstructive pulmonary disease	20	1
Cough variant asthma	6	0
Obstructive airways disorder	9	0
Reversible airways obstruction	1	0
Wheezing	407	0
<i><b>Conditions associated with abnormal gas exchange</b></i>		
Asphyxia	2	0
Cyanosis central	1	0
Hyperoxia	1	0
Hypoxia	30	2
Respiratory acidosis	2	0
<i><b>Coughing and associated symptoms</b></i>		
Allergic cough	7	0
Cough	2529	2
Cough decreased	2	0
Haemoptysis	62	0
Productive cough	175	0
Sputum discoloured	9	0
Sputum increased	3	0
<i><b>Diaphragmatic disorders</b></i>		
Acquired diaphragmatic eventration	1	0
Diaphragm muscle weakness	1	0
<i><b>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</b></i>		
Laryngeal disorder	1	0
Reflux laryngitis	2	0

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
Vocal cord disorder	1	0
Vocal cord dysfunction	2	0
<b><i>Laryngeal spasm, oedema and obstruction</i></b>		
Epiglottic oedema	1	0
Laryngeal obstruction	1	0
Laryngeal oedema	4	0
Laryngospasm	1	0
Stridor	24	0
<b><i>Lower respiratory tract inflammatory and immunologic conditions</i></b>		
Alveolitis	1	0
Autoimmune lung disease	1	0
Hypersensitivity pneumonitis	1	0
Lower respiratory tract inflammation	1	0
Pneumonitis	29	1
Pulmonary sarcoidosis	2	0
<b><i>Lower respiratory tract signs and symptoms</i></b>		
Hiccups	33	0
Increased bronchial secretion	2	0
Increased viscosity of bronchial secretion	1	0
Lung hyperinflation	2	0
Lung opacity	2	0
Pleuritic pain	21	0
Pulmonary haemorrhage	1	0
Pulmonary pain	97	0
Rales	5	0
Respiratory fremitus	1	0
<b><i>Mediastinal disorders</i></b>		
Mediastinal mass	1	0
Pulmonary hilum mass	1	0
<b><i>Nasal congestion and inflammations</i></b>		
Nasal congestion	291	0
Nasal inflammation	3	0
Rhinitis allergic	20	0
<b><i>Nasal disorders NEC</i></b>		
Epistaxis	935	0
Intranasal hypoaesthesia	2	0
Intranasal paraesthesia	1	0
Nasal crusting	2	0
Nasal disorder	3	0
Nasal dryness	36	0
Nasal mucosal discolouration	1	0
Nasal odour	6	0
Nasal oedema	8	0
Nasal polyps	1	0
Nasal pruritus	12	0
Nasal ulcer	1	0
<b><i>Neonatal hypoxic conditions</i></b>		
Dry lung syndrome	1	0
Gasping syndrome	1	0
Infantile apnoea	2	0
<b><i>Paranasal sinus disorders (excl infections and neoplasms)</i></b>		
Allergic sinusitis	1	0
Paranasal sinus inflammation	4	0

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
Sinonasal obstruction	11	0
Sinus congestion	64	0
Sinus disorder	6	0
<b><i>Parenchymal lung disorders NEC</i></b>		
Atelectasis	3	0
Combined pulmonary fibrosis and emphysema	1	0
Emphysema	3	0
Interstitial lung disease	10	0
Lung consolidation	5	0
Lung infiltration	2	1
Organising pneumonia	1	0
Pulmonary alveolar haemorrhage	1	0
Pulmonary cavitation	1	0
Pulmonary fibrosis	8	0
<b><i>Pharyngeal disorders (excl infections and neoplasms)</i></b>		
Hyperactive pharyngeal reflex	1	0
Pharyngeal enanthema	1	0
Pharyngeal erythema	7	0
Pharyngeal haemorrhage	2	0
Pharyngeal hypoaesthesia	37	0
Pharyngeal inflammation	4	0
Pharyngeal lesion	1	0
Pharyngeal mass	1	0
Pharyngeal oedema	14	0
Pharyngeal paraesthesia	54	0
Pharyngeal swelling	255	0
Pharyngeal ulceration	14	0
Tonsillar erythema	11	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	84	0
Tonsillar inflammation	3	0
Tonsillar ulcer	1	0
Tonsilloolith	1	0
<b><i>Pleural infections and inflammations</i></b>		
Pleurisy	35	0
<b><i>Pneumothorax and pleural effusions NEC</i></b>		
Pleural effusion	32	0
Pneumothorax	8	0
Pneumothorax spontaneous	3	0
<b><i>Pulmonary hypertension</i></b>		
Pulmonary hypertension	3	0
<b><i>Pulmonary oedemas</i></b>		
Acute respiratory distress syndrome	2	1
Pulmonary congestion	17	0
Pulmonary oedema	21	2
<b><i>Pulmonary thrombotic and embolic conditions</i></b>		
Pulmonary artery thrombosis	1	0
Pulmonary embolism	442	32
Pulmonary infarction	6	0
Pulmonary thrombosis	8	1
<b><i>Respiratory failures (excl neonatal)</i></b>		
Acute respiratory failure	3	1
Respiratory failure	12	2

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
<b><i>Respiratory signs and symptoms NEC</i></b>		
Allergic respiratory symptom	6	0
Diaphragmalgia	7	0
Nasal flaring	1	0
Painful respiration	12	1
Pleural rub	1	0
Respiratory symptom	19	0
Suffocation feeling	2	0
Use of accessory respiratory muscles	1	0
<b><i>Respiratory tract disorders NEC</i></b>		
Aspiration	3	0
Lung disorder	7	1
Pulmonary mass	4	0
Respiratory disorder	15	1
Respiratory tract congestion	4	0
Respiratory tract haemorrhage	1	0
Respiratory tract inflammation	2	0
Respiratory tract irritation	9	0
Respiratory tract oedema	4	0
<b><i>Thoracic musculoskeletal disorders</i></b>		
Respiratory muscle weakness	2	0
<b><i>Tracheal disorders (excl infections and neoplasms)</i></b>		
Tracheal disorder	1	0
Tracheal pain	2	0
<b><i>Upper respiratory tract neoplasms</i></b>		
Tonsillar cyst	1	0
<b><i>Upper respiratory tract signs and symptoms</i></b>		
Aphonia	121	0
Catarrh	29	0
Choking	17	0
Choking sensation	5	0
Dry throat	171	0
Dysphonia	160	0
Increased upper airway secretion	6	0
Increased viscosity of upper respiratory secretion	32	0
Laryngeal pain	1	0
Nasal discharge discolouration	3	0
Nasal discomfort	49	0
Nasal obstruction	2	0
Oropharyngeal blistering	11	0
Oropharyngeal discomfort	69	0
Oropharyngeal pain	2867	0
Oropharyngeal plaque	2	0
Paranasal sinus discomfort	46	0
Rhinalgia	11	0
Rhinorrhoea	918	0
Sinus pain	217	0
Sneezing	383	0
Snoring	7	0
Throat clearing	8	0
Throat irritation	231	0
Throat tightness	262	0
Upper airway obstruction	2	0

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
Upper respiratory tract congestion	2	0
Upper respiratory tract irritation	1	0
Upper-airway cough syndrome	11	0
Yawning	27	0
<b><i>Vascular pulmonary disorders NEC</i></b>		
Acute chest syndrome	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>17639</b>	<b>55</b>

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Acnes</i></b>		
Acne	188	0
Acne cystic	23	0
Dermatitis acneiform	12	0
<b><i>Alopecias</i></b>		
Alopecia	305	0
Alopecia areata	47	0
Alopecia totalis	3	0
Androgenetic alopecia	2	0
Diffuse alopecia	3	0
Hypotrichosis	1	0
Lichen planopilaris	1	0
Madarosis	6	0
<b><i>Angioedemas</i></b>		
Angioedema	225	0
Circumoral swelling	1	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Anhidrosis	1	0
Bromhidrosis	1	0
Cold sweat	777	0
Hidradenitis	4	0
Hyperhidrosis	2291	0
Hypohidrosis	2	0
Milia	2	0
Miliaria	94	0
Night sweats	679	0
Sweat discolouration	1	0
<b><i>Bullous conditions</i></b>		
Blister	462	0
Blister rupture	1	0
Blood blister	29	0
Dermatitis bullous	12	0
Erythema multiforme	38	0
Fracture blisters	1	0
Herpes gestationis	1	0
Pemphigoid	27	0
Pemphigus	9	0
Stevens-Johnson syndrome	6	0
Toxic epidermal necrolysis	2	1
<b><i>Connective tissue disorders</i></b>		
Cutaneous lupus erythematosus	2	0
Dermatomyositis	7	0
Subacute cutaneous lupus erythematosus	1	0
<b><i>Dermal and epidermal conditions NEC</i></b>		
Acute febrile neutrophilic dermatosis	1	0
Dermatosis	1	0
Dry skin	235	0
Koebner phenomenon	1	0
Macule	5	0
Neutrophilic dermatosis	1	0
Pain of skin	278	0
Papule	108	0
Pathergy reaction	1	0

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Scab	22	0
Scar pain	15	0
Sensitive skin	179	0
Shagreen skin	1	0
Skin burning sensation	227	0
Skin degenerative disorder	1	0
Skin discolouration	134	0
Skin discomfort	4	0
Skin disorder	29	0
Skin fissures	8	0
Skin indentation	2	0
Skin induration	5	0
Skin lesion	44	0
Skin lesion inflammation	1	0
Skin necrosis	2	0
Skin odour abnormal	20	0
Skin plaque	3	0
Skin reaction	146	0
Skin sensitisation	39	0
Skin swelling	95	0
Skin texture abnormal	2	0
Skin tightness	26	0
Skin warm	307	0
Skin weeping	11	0
Sticky skin	3	0
Target skin lesion	3	0
Transient acantholytic dermatosis	1	0
Yellow skin	25	0
<b><i>Dermatitis and eczema</i></b>		
Dermatitis	136	0
Dermatitis allergic	243	0
Dermatitis atopic	41	0
Dermatitis contact	20	0
Dermatitis diaper	4	0
Dyshidrotic eczema	28	0
Eczema	326	0
Eczema asteatotic	11	0
Eczema infantile	1	0
Eczema nummular	5	0
Eczema weeping	3	0
Hand dermatitis	2	0
Intertrigo	1	0
Neurodermatitis	3	0
Perioral dermatitis	2	0
Seborrhoeic dermatitis	5	0
Skin irritation	120	0
Stasis dermatitis	1	0
<b><i>Dermatitis ascribed to specific agent</i></b>		
Drug eruption	33	0
Drug reaction with eosinophilia and systemic symptoms	2	0
Fixed eruption	2	0
Palmar-plantar erythrodysesthesia syndrome	1	0
Toxic skin eruption	2	0

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
<b><i>Erythemas</i></b>		
Erythema	2182	0
Palmar erythema	4	0
Red man syndrome	2	0
<b><i>Exfoliative conditions</i></b>		
Dermatitis exfoliative	2	0
Dermatitis exfoliative generalised	5	0
Exfoliative rash	20	0
Keratolysis exfoliativa acquired	2	0
Skin exfoliation	121	0
<b><i>Granulomatous and deep cutaneous inflammatory conditions</i></b>		
Cutaneous sarcoidosis	1	0
Granuloma annulare	5	0
Necrobiosis lipoidica diabetorum	1	0
<b><i>Hyperkeratoses</i></b>		
Hyperkeratosis	1	0
Keratosis pilaris	3	0
Lichenoid keratosis	3	0
<b><i>Hyperpigmentation disorders</i></b>		
Argyria	1	0
Chloasma	1	0
Ephelides	1	0
Skin hyperpigmentation	6	0
Solar lentigo	3	0
<b><i>Hypertrichoses</i></b>		
Hirsutism	2	0
Hypertrichosis	1	0
<b><i>Hypopigmentation disorders</i></b>		
Skin depigmentation	4	0
Skin hypopigmentation	1	0
Vitiligo	18	0
<b><i>Lipodystrophies</i></b>		
Lipoatrophy	4	0
Lipodystrophy acquired	1	0
<b><i>Nail and nail bed conditions (excl infections and infestations)</i></b>		
Nail discolouration	11	0
Nail disorder	3	0
Nail pigmentation	2	0
Nail ridging	3	0
Onychalgia	8	0
Onychoclasia	5	0
Onychomadesis	2	0
Splinter haemorrhages	3	0
<b><i>Panniculitides</i></b>		
Erythema nodosum	26	0
Panniculitis	1	0
<b><i>Papulosquamous conditions</i></b>		
Erythema annulare	2	0
Lichen planus	20	0
Lichen sclerosus	9	0
Parapsoriasis	4	0
Pityriasis rosea	119	0
Pityriasis rubra pilaris	1	0



## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
<b><i>Photosensitivity and photodermatosis conditions</i></b>		
Photosensitivity reaction	64	0
Polymorphic light eruption	3	0
Solar dermatitis	2	0
<b><i>Pigmentation changes NEC</i></b>		
Haemosiderin stain	1	0
Pigmentation disorder	15	0
<b><i>Pilar disorders NEC</i></b>		
Hair colour changes	10	0
Hair disorder	1	0
Hair growth abnormal	5	0
Hair texture abnormal	6	0
Piloerection	27	0
Pseudofolliculitis	3	0
Trichorrhexis	3	0
<b><i>Pruritus NEC</i></b>		
Itching scar	7	0
Pruritus	5434	0
<b><i>Psoriatic conditions</i></b>		
Dermatitis psoriasiform	5	0
Guttate psoriasis	18	0
Nail psoriasis	2	0
Palmoplantar pustulosis	2	0
Psoriasis	195	0
Pustular psoriasis	3	0
Rebound psoriasis	1	0
<b><i>Purpura and related conditions</i></b>		
Ecchymosis	1	0
Henoch-Schonlein purpura	11	0
Petechiae	142	0
Purpura	58	0
<b><i>Pustular conditions</i></b>		
Acute generalised exanthematous pustulosis	2	0
<b><i>Rashes, eruptions and exanthems NEC</i></b>		
Butterfly rash	5	0
Rash	5721	1
Rash erythematous	1196	0
Rash macular	501	0
Rash maculo-papular	62	0
Rash morbilliform	44	0
Rash papular	346	0
Rash pruritic	1204	0
Rash vesicular	75	0
Systemic lupus erythematosus rash	7	0
<b><i>Rosaceas</i></b>		
Rosacea	32	0
<b><i>Scaly conditions</i></b>		
Dandruff	5	0
Pityriasis	25	0
<b><i>Sebaceous gland disorders</i></b>		
Seborrhoea	10	0
<b><i>Skin and subcutaneous conditions NEC</i></b>		
Cellulite	2	0

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Cutaneous symptom	5	0
Reactive perforating collagenosis	1	0
Skin mass	20	0
<b><i>Skin and subcutaneous tissue ulcerations</i></b>		
Ischaemic skin ulcer	1	0
Mucocutaneous ulceration	1	0
Pyoderma gangrenosum	1	0
Scleroderma associated digital ulcer	1	0
Skin erosion	24	0
Skin ulcer	21	0
<b><i>Skin cysts and polyps</i></b>		
Dermal cyst	13	0
<b><i>Skin dystrophies</i></b>		
Keloid scar	3	0
Skin wrinkling	2	0
<b><i>Skin haemorrhages</i></b>		
Haemorrhage subcutaneous	15	0
Skin haemorrhage	19	0
<b><i>Skin hyperplasias and hypertrophies</i></b>		
Skin hypertrophy	2	0
<b><i>Skin hypoplasias and atrophies</i></b>		
Skin atrophy	3	0
Skin striae	7	0
<b><i>Skin injuries and mechanical dermatoses</i></b>		
Decubitus ulcer	2	0
Needle track marks	4	0
<b><i>Skin preneoplastic conditions NEC</i></b>		
Actinic keratosis	1	0
<b><i>Skin vascular conditions NEC</i></b>		
Angiodermatitis	1	0
Skin oedema	4	0
<b><i>Skin vasculitides</i></b>		
Capillaritis	2	0
Cutaneous vasculitis	14	0
Hypersensitivity vasculitis	1	0
Vasculitic rash	21	0
<b><i>Skin vasomotor conditions</i></b>		
Livedo reticularis	23	0
<b><i>Telangiectasia and related conditions</i></b>		
Spider naevus	1	0
Telangiectasia	1	0
<b><i>Urticarias</i></b>		
Chronic spontaneous urticaria	12	0
Cold urticaria	7	0
Idiopathic urticaria	1	0
Mechanical urticaria	9	0
Solar urticaria	2	0
Urticaria	1887	0
Urticaria cholinergic	2	0
Urticaria chronic	23	0
Urticaria contact	1	0
Urticaria papular	4	0
Urticaria thermal	7	0

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Urticarial vasculitis	5	0
<b>Skin disorders SOC TOTAL</b>	<b>28289</b>	<b>2</b>

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i><b>Age related issues</b></i>		
Infant	2	0
Menarche	3	0
Menopause	39	0
Postmenopause	3	0
<i><b>Criminal activity</b></i>		
Verbal abuse	1	0
<i><b>Dependents</b></i>		
Sick relative	5	0
<i><b>Dietary and nutritional issues</b></i>		
Feeding tube user	1	0
<i><b>Disability issues</b></i>		
Bedridden	25	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	15	0
Loss of personal independence in daily activities	40	0
Physical disability	5	0
Sight disability	11	0
Sitting disability	4	0
Walking disability	1	0
Wheelchair user	1	0
<i><b>Economic circumstances</b></i>		
High income	1	0
Low income	1	0
<i><b>Educational issues</b></i>		
Educational problem	1	0
Illiteracy	1	0
<i><b>Employment issues</b></i>		
Job dissatisfaction	1	0
Retirement	4	0
Sick leave	1	0
Stress at work	3	0
<i><b>Family and partner issues</b></i>		
Bed sharing	1	0
<i><b>Non-occupational and unspecified environmental problems</b></i>		
Flooding	1	0
Water pollution	2	0
<i><b>Pregnancy related circumstances</b></i>		
Breast feeding	16	0
Multigravida	1	0
Parity	1	0
<i><b>Social issues NEC</b></i>		
Exercise adequate	2	0
Hair dye user	2	0
Impaired quality of life	3	0
<i><b>Tobacco use</b></i>		
Ex-tobacco user	1	0
Non-tobacco user	4	0

# Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Social circumstances</b> Social circumstances cont'd		
Tobacco user	1	0
<b>Social circumstances SOC TOTAL</b>	<b>228</b>	<b>0</b>

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i><b>Anaesthesia and allied procedures</b></i>		
Local anaesthesia	2	0
Nerve block	5	0
<i><b>Analgesia supportive care</b></i>		
Analgesic therapy	1	0
<i><b>Antiinfective therapies</b></i>		
COVID-19 prophylaxis	1	0
COVID-19 treatment	4	0
<i><b>Arterial therapeutic procedures (excl aortic)</b></i>		
Splenic artery embolisation	1	0
<i><b>Blood and blood product treatment</b></i>		
Transfusion	2	0
<i><b>Breast therapeutic procedures NEC</b></i>		
Axillary lymphadenectomy	3	0
Mammoplasty	1	0
<i><b>Bronchial and pulmonary therapeutic procedures</b></i>		
Airway secretion clearance therapy	1	0
<i><b>Cardiac device therapeutic procedures</b></i>		
Cardiac pacemaker insertion	1	0
<i><b>Cardiac therapeutic procedures NEC</b></i>		
Cardiac operation	1	0
<i><b>Contraceptive methods female</b></i>		
Contraception	1	0
Contraceptive implant	3	0
Oral contraception	1	0
<i><b>Contraceptive methods male</b></i>		
Condom	1	0
<i><b>Dietary and nutritional therapies</b></i>		
Medical diet	8	0
Nothing by mouth order	12	0
Wheat-free diet	1	0
<i><b>External ear therapeutic procedures</b></i>		
Ear irrigation	1	0
<i><b>Fertility and fertilisation interventions female</b></i>		
Endometrial scratching	1	0
<i><b>Gastrointestinal therapeutic procedures NEC</b></i>		
Intestinal anastomosis	1	0
Prophylaxis of nausea and vomiting	15	0
<i><b>Gynaecological therapeutic procedures NEC</b></i>		
Menstrual cycle management	12	0
<i><b>Haematological therapeutic procedures NEC</b></i>		
Anticoagulant therapy	1	0
<i><b>Head, neck and oral cavity therapeutic procedures NEC</b></i>		
Neck lift	1	0
<i><b>Hernia repairs</b></i>		
Hernia repair	1	0
<i><b>Hormonal therapeutic procedures NEC</b></i>		
Hormone replacement therapy	1	0
Hormone therapy	8	0
<i><b>Immunisations</b></i>		
COVID-19 immunisation	101	0
Immunisation	289	1
<i><b>Induced abortions</b></i>		

## Case Series Drug Analysis Print

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

Report Run Date: 10-Dec-2021

Data Lock Date: 08-Dec-2021 18:30:07

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
Surgical & medical procedures cont'd		
Abortion induced	2	0
<b>Joint therapeutic procedures</b>		
Joint injection	4	0
Joint surgery	1	0
Knee arthroplasty	1	0
<b>Large intestine therapeutic procedures</b>		
Appendectomy	3	0
<b>Limb therapeutic procedures</b>		
Arm amputation	1	0
Limb immobilisation	10	0
Limb operation	7	0
<b>Lymphoid tissue therapeutic procedures</b>		
Lymphadenectomy	3	0
Splenectomy	1	0
<b>Mastectomies</b>		
Breast conserving surgery	4	0
<b>Nail therapeutic procedures</b>		
Nail operation	3	0
<b>Nervous system therapeutic procedures NEC</b>		
Multiple sclerosis relapse prophylaxis	2	0
<b>Obstetric therapeutic procedures</b>		
Caesarean section	1	0
Labour stimulation	1	0
<b>Orbit and globe therapeutic procedures</b>		
Strabismus correction	1	0
<b>Ovarian therapeutic procedures</b>		
Ovarian operation	1	0
<b>Peripheral nerve therapeutic procedures</b>		
Neurolysis	1	0
Peripheral nerve neurostimulation	1	0
<b>Phototherapies</b>		
UV light therapy	1	0
<b>Prophylactic procedures NEC</b>		
Anaphylaxis prophylaxis	2	0
Immune tolerance induction	1	0
Prophylaxis against transplant rejection	1	0
Reproductive system disorder prophylaxis	1	0
<b>Psychiatric therapies</b>		
Electroconvulsive therapy	1	0
<b>Renal therapeutic procedures</b>		
Dialysis	1	0
<b>Respiratory tract therapeutic procedures NEC</b>		
Asthma prophylaxis	3	0
<b>Retinal therapeutic procedures</b>		
Retinopexy	1	0
<b>Skin and subcutaneous tissue therapeutic procedures NEC</b>		
Dermal filler injection	4	0
Therapeutic skin care topical	1	0
<b>Skull and brain therapeutic procedures</b>		
Cerebrovascular operation	1	0
Posterior fossa decompression	1	0
<b>Small intestine therapeutic procedures</b>		
Ileostomy	1	0

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<small>Surgical &amp; medical procedures cont'd</small>		
<b><i>Therapeutic bladder catheterisation</i></b>		
Bladder catheterisation	2	0
<b><i>Therapeutic procedures NEC</i></b>		
Abscess drainage	1	0
Anaphylaxis treatment	7	0
Bed rest	5	0
Fatigue management	1	0
Hospitalisation	14	0
Injection	59	0
Interchange of vaccine products	77	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	3	0
Promotion of wound healing	1	0
Specialist consultation	1	0
Stoma care	1	0
Therapeutic procedure	1	0
Therapy change	1	0
<b><i>Tracheal therapeutic procedures</i></b>		
Tracheostomy	1	0
<b><i>Uterine therapeutic procedures</i></b>		
Endometrial ablation	2	0
<b><i>Vascular therapeutic procedures NEC</i></b>		
Vasodilation procedure	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>738</b>	<b>1</b>



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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<b><i>Accelerated and malignant hypertension</i></b>		
Hypertensive crisis	12	0
Hypertensive urgency	2	0
Malignant hypertension	4	0
<b><i>Aneurysms and dissections non-site specific</i></b>		
Aneurysm	2	0
Artery dissection	2	0
<b><i>Aortic aneurysms and dissections</i></b>		
Acute aortic syndrome	1	0
Aortic aneurysm rupture	1	1
Aortic dissection	1	0
<b><i>Aortic embolism and thrombosis</i></b>		
Aortic embolus	5	0
Aortic thrombosis	4	0
<b><i>Aortic infections and inflammations</i></b>		
Aortitis	1	0
<b><i>Aortic necrosis and vascular insufficiency</i></b>		
Aortic occlusion	1	0
<b><i>Arterial infections and inflammations</i></b>		
Arteritis	1	0
Giant cell arteritis	15	0
<b><i>Blood pressure disorders NEC</i></b>		
Blood pressure fluctuation	13	0
Labile blood pressure	3	0
<b><i>Bruising, ecchymosis and purpura</i></b>		
Achenbach syndrome	4	0
<b><i>Circulatory collapse and shock</i></b>		
CT hypotension complex	2	0
Circulatory collapse	75	0
Hypoperfusion	2	0
Hypovolaemic shock	1	1
Neurogenic shock	22	0
Peripheral circulatory failure	6	0
Shock	21	0
<b><i>Haemorrhages NEC</i></b>		
Arterial haemorrhage	1	0
Bloody discharge	24	0
Haematoma	50	0
Haemorrhage	1191	2
Internal haemorrhage	10	0
Venous haemorrhage	2	0
<b><i>Lymphangiopathies</i></b>		
Lymphangiopathy	1	0
Lymphocele	5	0
Lymphorrhoea	1	0
<b><i>Lymphoedemas</i></b>		
Lymphoedema	212	0
<b><i>Non-site specific embolism and thrombosis</i></b>		
Arterial thrombosis	4	0
Embolism	62	0
Embolism venous	7	0
Microembolism	1	0
Thrombosis	429	8

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Reaction Name	Total	Fatal
<b>Vascular disorders</b> <small>Vascular disorders cont'd</small>		
Venous thrombosis	7	0
<b><i>Non-site specific necrosis and vascular insufficiency NEC</i></b>		
Arterial occlusive disease	2	0
Arterial spasm	1	0
Arteriosclerosis	3	0
Haemorrhagic infarction	1	0
Infarction	3	0
Ischaemia	10	0
Peripheral venous disease	1	0
Vascular occlusion	1	0
Vasospasm	1	0
<b><i>Non-site specific vascular disorders NEC</i></b>		
Capillary disorder	1	0
Capillary fragility	4	0
Superficial vein prominence	2	0
Vascular pain	32	0
Vascular wall hypertrophy	1	0
Vasodilatation	36	0
Vein discolouration	5	0
Vein disorder	6	0
Vein rupture	5	0
<b><i>Peripheral aneurysms and dissections</i></b>		
Peripheral artery aneurysm	1	0
<b><i>Peripheral embolism and thrombosis</i></b>		
Axillary vein thrombosis	1	0
Blue toe syndrome	28	0
Deep vein thrombosis	295	1
Femoral artery embolism	1	0
Jugular vein thrombosis	3	0
Pelvic venous thrombosis	4	0
Peripheral artery thrombosis	2	0
Peripheral embolism	2	0
Subclavian vein thrombosis	3	0
Superficial vein thrombosis	23	0
Thrombophlebitis	26	0
<b><i>Peripheral vascular disorders NEC</i></b>		
Cyanosis	46	0
Erythromelalgia	2	0
Flushing	424	0
Hot flush	1131	0
Peripheral vascular disorder	1	0
Vein wall hypertrophy	1	0
<b><i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i></b>		
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	339	0
Peripheral ischaemia	12	0

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Reaction Name	Total	Fatal
<b>Vascular disorders</b> <small>Vascular disorders cont'd</small>		
Poor peripheral circulation	17	0
Raynaud's phenomenon	57	0
Subclavian vein occlusion	1	0
Vasoconstriction	2	0
<b>Phlebitis NEC</b>		
Phlebitis	33	0
Phlebitis superficial	8	0
<b>Site specific vascular disorders NEC</b>		
Aortic disorder	1	0
Inferior vena cava dilatation	1	0
Pallor	389	0
<b>Varicose veins NEC</b>		
Spider vein	6	0
Varicophlebitis	4	0
Varicose vein	31	0
<b>Vascular hypertensive disorders NEC</b>		
Diastolic hypertension	5	0
Essential hypertension	3	0
Hypertension	616	0
Labile hypertension	1	0
Orthostatic hypertension	1	0
Secondary hypertension	1	0
Systolic hypertension	7	0
White coat hypertension	1	0
<b>Vascular hypotensive disorders</b>		
Capillary leak syndrome	1	0
Diastolic hypotension	1	0
Hypotension	395	1
Orthostatic hypotension	31	0
<b>Vasculitides NEC</b>		
Behcet's syndrome	5	0
Diffuse vasculitis	1	0
Granulomatosis with polyangiitis	2	0
MAGIC syndrome	1	0
Thromboangiitis obliterans	1	0
Vasculitis	49	0
<b>Vena caval embolism and thrombosis</b>		
Vena cava embolism	1	0
Vena cava thrombosis	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>6356</b>	<b>14</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>405234</b>	<b>650</b>
<b>TOTAL REPORTS</b>	<b>141866</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>650</b>