



## Case Series Drug Analysis Print

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

Report Run Date: 17-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

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	5	0
Deficiency anaemia	1	0
Iron deficiency anaemia	8	0
Pernicious anaemia	2	0
<b><i>Anaemias NEC</i></b>		
Anaemia	142	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	19	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	54	0
Spontaneous haematoma	2	0
<b><i>Coagulation factor deficiencies</i></b>		
Acquired factor VIII deficiency	1	0
Acquired haemophilia	4	0
<b><i>Coagulopathies</i></b>		
Abnormal clotting factor	4	0
Antiphospholipid syndrome	6	0
Coagulopathy	27	1
Disseminated intravascular coagulation	3	0
Hypercoagulation	3	0
Thrombotic microangiopathy	4	0
<b><i>Eosinophilic disorders</i></b>		
Eosinophilia	13	0
<b><i>Haematological disorders</i></b>		
Blood disorder	6	0
Bone marrow disorder	1	0
Bone marrow oedema	1	0
Hypergammaglobulinaemia	1	0
Hyperviscosity syndrome	1	0
Mast cell activation syndrome	10	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	3	0

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<b>Blood disorders</b> Blood disorders cont'd		
Lymphocytic infiltration	1	0
Lymphocytosis	6	0
Neutrophilia	12	0
<b>Leukopenias NEC</b>		
Leukopenia	4	1
Lymphopenia	4	0
<b>Lymphatic system disorders NEC</b>		
Abdominal lymphadenopathy	4	0
Hilar lymphadenopathy	3	0
Lymph node pain	2251	0
Lymph node ulcer	1	0
Lymphadenitis	179	0
Lymphadenopathy	13534	0
Lymphadenopathy mediastinal	1	0
Lymphatic disorder	3	0
Lymphatic insufficiency	1	0
Necrotic lymphadenopathy	4	0
Pseudolymphoma	12	0
Retroperitoneal lymphadenopathy	1	0
<b>Marrow depression and hypoplastic anaemias</b>		
Aplasia pure red cell	2	0
Aplastic anaemia	1	1
Hypoplastic anaemia	2	0
Myelosuppression	1	0
Pancytopenia	8	0
<b>Neutropenias</b>		
Autoimmune neutropenia	2	0
Neutropenia	41	0
<b>Platelet disorders NEC</b>		
Platelet anisocytosis	1	0
Platelet disorder	3	0
<b>Polycythaemia (excl rubra vera)</b>		
Polycythaemia	3	0
<b>Purpuras (excl thrombocytopenic)</b>		
Purpura non-thrombocytopenic	1	0
<b>Red blood cell abnormal findings NEC</b>		
Macrocytosis	2	0
Polychromasia	2	0
Red blood cell abnormality	2	0
<b>Spleen disorders</b>		
Spleen atrophy	1	0
Splenic infarction	3	0
Splenic lesion	1	0
Splenic thrombosis	2	0
Splenic vein thrombosis	2	0
Splenomegaly	12	0
<b>Thrombocytopenias</b>		
Acquired amegakaryocytic thrombocytopenia	1	0
Immune thrombocytopenia	82	0
Thrombocytopenia	236	1
Thrombocytopenic purpura	8	0
Thrombotic thrombocytopenic purpura	6	0
<b>Thrombocytoses</b>		

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Reaction Name	Total	Fatal
<b>Blood disorders</b> Blood disorders cont'd		
Thrombocytosis	7	0
<b>Blood disorders SOC TOTAL</b>	<b>16805</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	2	0
<i><b>Cardiac conduction disorders</b></i>		
Atrioventricular block	31	1
Atrioventricular block complete	3	1
Atrioventricular block first degree	2	0
Atrioventricular block second degree	4	0
Bundle branch block	2	0
Bundle branch block left	4	0
Bundle branch block right	4	0
Trifascicular block	1	0
<i><b>Cardiac disorders NEC</b></i>		
Acute cardiac event	7	0
Cardiac disorder	90	2
Cardiac dysfunction	2	0
Cardiac ventricular thrombosis	2	0
Cardiovascular deconditioning	1	0
Cardiovascular disorder	8	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	9	0
<i><b>Cardiac neoplasms NEC</b></i>		
Pericardial cyst	1	0
<i><b>Cardiac signs and symptoms NEC</b></i>		
Cardiac discomfort	35	0
Cardiovascular symptom	2	0
Palpitations	5869	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	14	0
Congestive cardiomyopathy	8	0
Stress cardiomyopathy	3	0
<i><b>Coronary artery disorders NEC</b></i>		
Arteriosclerosis coronary artery	1	0
Coronary artery disease	9	3
Coronary artery dissection	1	0
Coronary artery occlusion	3	0
Coronary artery thrombosis	5	2
<i><b>Endocarditis NEC</b></i>		
Endocarditis noninfective	1	1
<i><b>Heart failures NEC</b></i>		
Cardiac failure	83	10
Cardiac failure acute	6	1
Cardiac failure chronic	2	0
Cardiac failure congestive	6	3
Cardiogenic shock	4	1
Cardiopulmonary failure	1	1
<i><b>Ischaemic coronary artery disorders</b></i>		
Acute coronary syndrome	8	1

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b> Cardiac disorders cont'd		
Acute myocardial infarction	28	2
Angina pectoris	313	1
Angina unstable	4	0
Arteriospasm coronary	4	0
Microvascular coronary artery disease	3	0
Myocardial infarction	283	41
Myocardial ischaemia	11	7
<b>Left ventricular failures</b>		
Acute left ventricular failure	1	1
Left ventricular failure	7	2
<b>Mitral valvular disorders</b>		
Mitral valve incompetence	8	0
Mitral valve prolapse	1	0
<b>Myocardial disorders NEC</b>		
Cardiac amyloidosis	1	0
Cardiac aneurysm	1	1
Cardiac ventricular scarring	1	0
Cardiomegaly	48	3
Dilatation ventricular	1	0
Left atrial dilatation	1	0
Left ventricular dysfunction	14	0
Left ventricular enlargement	2	0
Left ventricular hypertrophy	2	0
Myocardial fibrosis	7	0
Myocardial haemorrhage	1	0
Myocardial injury	21	0
Myocardial necrosis	1	0
Myocardial oedema	7	0
Myocardial rupture	1	0
Right atrial enlargement	1	0
Right ventricular dilatation	1	0
Right ventricular dysfunction	2	0
Right ventricular enlargement	1	0
Ventricular dysfunction	2	0
Ventricular hypertrophy	1	0
Ventricular hypokinesia	4	0
<b>Noninfectious myocarditis</b>		
Eosinophilic myocarditis	1	0
Hypersensitivity myocarditis	1	0
Myocarditis	721	1
Myocarditis post infection	1	0
<b>Noninfectious pericarditis</b>		
Pericarditis	483	2
Pericarditis constrictive	1	0
Pericarditis lupus	1	0
Pleuropericarditis	1	0
<b>Pericardial disorders NEC</b>		
Cardiac tamponade	2	1
Pericardial effusion	43	2
Pericardial fibrosis	1	0
Pericardial haemorrhage	4	3
Pericardial rub	2	0
<b>Rate and rhythm disorders NEC</b>		

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<b>Cardiac disorders</b> Cardiac disorders cont'd		
Arrhythmia	182	1
Arrhythmia neonatal	1	0
Bradycardia	74	0
Bradycardia foetal	2	0
Cardiac flutter	599	0
Extrasystoles	212	0
Heart alternation	3	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	32	0
Tachyarrhythmia	9	0
Tachycardia	2296	0
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	16	0
Atrial fibrillation	277	1
Atrial flutter	44	0
Atrial tachycardia	11	0
Nodal arrhythmia	1	0
Sinus arrest	1	0
Sinus arrhythmia	8	0
Sinus bradycardia	13	0
Sinus node dysfunction	1	0
Sinus tachycardia	77	0
Supraventricular extrasystoles	6	0
Supraventricular tachycardia	46	0
<b>Tricuspid valvular disorders</b>		
Tricuspid valve incompetence	6	0
<b>Ventricular arrhythmias and cardiac arrest</b>		
Cardiac arrest	124	45
Cardio-respiratory arrest	1	1
Pulseless electrical activity	6	0
Ventricular arrhythmia	5	0
Ventricular extrasystoles	31	0
Ventricular fibrillation	10	1
Ventricular tachycardia	15	0
<b>Cardiac disorders SOC TOTAL</b>	<b>12407</b>	<b>145</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<b><i>Autosomal chromosomal abnormalities</i></b>		
Trisomy 8	1	0
<b><i>Cardiac disorders congenital NEC</i></b>		
Heart disease congenital	18	0
<b><i>Cardiac hypoplasias congenital</i></b>		
Ventricular hypoplasia	1	0
<b><i>Cardiac septal defects congenital</i></b>		
Atrial septal defect	2	0
Hypertrophic cardiomyopathy	1	0
Ventricular septal defect	1	0
<b><i>Cardiac valve disorders congenital</i></b>		
Bicuspid aortic valve	1	0
<b><i>Central nervous system disorders congenital NEC</i></b>		
Spina bifida	2	1
Syringomyelia	1	0
<b><i>Cerebellar disorders congenital</i></b>		
Arnold-Chiari malformation	1	0
Hereditary ataxia	1	0
<b><i>Cerebral disorders congenital</i></b>		
Anencephaly	2	0
Cerebral palsy	4	0
Congenital hydrocephalus	1	0
<b><i>Chromosomal abnormalities NEC</i></b>		
Cytogenetic abnormality	1	0
<b><i>Coagulation disorders congenital</i></b>		
Factor IX deficiency	1	0
Haemophilia	2	0
<b><i>Congenital disorders NEC</i></b>		
Congenital anomaly	1	0
Foetal malformation	1	0
Heterotaxia	1	0
<b><i>Connective tissue disorders congenital</i></b>		
Ehlers-Danlos syndrome	5	0
<b><i>Gastrointestinal tract disorders congenital NEC</i></b>		
Gastroschisis	3	0
<b><i>Genetic polymorphisms</i></b>		
Genetic polymorphism	1	0
<b><i>Great vessel disorders congenital</i></b>		
Congenital great vessel anomaly	1	0
Transposition of the great vessels	1	0
<b><i>Haematological disorders congenital NEC</i></b>		
Amegakaryocytic thrombocytopenia	1	0
Neonatal alloimmune thrombocytopenia	1	0
<b><i>Haemoglobinopathies congenital</i></b>		
Congenital methaemoglobinaemia	1	0
<b><i>Immune system abnormalities congenital</i></b>		
Combined immunodeficiency	1	0
<b><i>Inborn errors of lipid metabolism</i></b>		
Short-chain acyl-coenzyme A dehydrogenase deficiency	1	0
<b><i>Inborn errors of metabolism NEC</i></b>		
Alpha-1 antitrypsin deficiency	1	0
<b><i>Inborn errors of porphyrin metabolism</i></b>		
Porphyria	1	0



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<b>Congenital disorders</b> Congenital disorders cont'd		
<b><i>Laryngeal and tracheal disorders congenital</i></b>		
Laryngomalacia	1	0
<b><i>Lymphatic system disorders congenital</i></b>		
Cystic lymphangioma	3	0
<b><i>Male reproductive tract disorders congenital</i></b>		
Cryptorchism	1	0
Micropenis	4	0
Penoscrotal fusion	1	0
Phimosis	1	0
<b><i>Musculoskeletal and connective tissue disorders of limbs congenital</i></b>		
Developmental hip dysplasia	1	0
Limb malformation	1	0
<b><i>Musculoskeletal and connective tissue disorders of skull congenital</i></b>		
Platybasia	1	0
<b><i>Musculoskeletal and connective tissue disorders of spine congenital</i></b>		
Block vertebra	1	0
Brachyolmia	1	0
<b><i>Musculoskeletal disorders congenital NEC</i></b>		
Dysmorphism	1	0
<b><i>Neurological disorders congenital NEC</i></b>		
Familial hemiplegic migraine	2	0
Familial periodic paralysis	1	0
Moebius II syndrome	1	0
Neurofibromatosis	1	0
Tourette's disorder	4	0
<b><i>Ocular disorders congenital NEC</i></b>		
Colour blindness	4	0
Congenital eye disorder	1	0
<b><i>Palate disorders congenital</i></b>		
Cleft lip and palate	2	0
<b><i>Peripheral nervous system disorders congenital NEC</i></b>		
Hereditary neuropathy with liability to pressure palsies	1	0
Paroxysmal extreme pain disorder	1	0
<b><i>Pulmonary and bronchial disorders congenital</i></b>		
Congenital cystic lung	1	0
<b><i>Retinal disorders congenital</i></b>		
Retinitis pigmentosa	1	0
<b><i>Sex chromosomal abnormalities</i></b>		
Turner's syndrome	1	0
<b><i>Skin and subcutaneous tissue disorders congenital NEC</i></b>		
Acral peeling skin syndrome	1	0
<b><i>Tongue disorders congenital</i></b>		
Ankyloglossia congenital	1	0
<b><i>Vascular anomalies congenital NEC</i></b>		
Congenital LUMBAR syndrome	1	0
<b><i>Venous disorders congenital</i></b>		
Anomalous pulmonary venous connection	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>104</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	39	0
Ear discomfort	102	0
Ear disorder	23	0
Ear haemorrhage	13	0
Ear inflammation	1	0
Ear pain	1147	0
Ear pruritus	12	0
Ear swelling	39	0
Otorrhoea	6	0
Paraesthesia ear	1	0
<i><b>Eustachian tube disorders</b></i>		
Eustachian tube disorder	5	0
Eustachian tube dysfunction	10	0
Eustachian tube obstruction	6	0
<i><b>External ear disorders NEC</b></i>		
Auricular swelling	2	0
Excessive cerumen production	12	0
External ear pain	6	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	290	0
Deafness bilateral	11	0
Deafness neurosensory	25	0
Deafness transitory	9	0
Deafness unilateral	37	0
Hypoacusis	223	0
Sudden hearing loss	52	0
<i><b>Hyperacusia</b></i>		
Hyperacusis	72	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	13	0
Vestibular disorder	15	0
<i><b>Inner ear infections and inflammations</b></i>		
Inner ear inflammation	11	0
<i><b>Inner ear signs and symptoms</b></i>		
Motion sickness	69	0
Phobic postural vertigo	1	0
Tinnitus	2379	0
Vertigo	1626	0
Vertigo labyrinthine	13	0
Vertigo positional	84	0
<i><b>Mastoid disorders</b></i>		

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Reaction Name	Total	Fatal
<b>Ear disorders</b> Ear disorders cont'd		
Mastoid effusion	1	0
<b>Middle ear disorders NEC</b>		
Middle ear disorder	3	0
Middle ear effusion	1	0
<b>Middle ear infections and inflammations</b>		
Middle ear inflammation	1	0
<b>Tympanic membrane disorders (excl infections)</b>		
Tympanic membrane perforation	3	0
<b>Ear disorders SOC TOTAL</b>	<b>6395</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	3	0
Thyroiditis	23	0
Thyroiditis acute	3	0
Thyroiditis subacute	7	0
<i><b>Adrenal cortical hypofunctions</b></i>		
Addison's disease	2	0
Adrenal insufficiency	3	0
Adrenocortical insufficiency acute	16	0
<i><b>Adrenal gland disorders NEC</b></i>		
Adrenal disorder	3	0
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
Luteal phase deficiency	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	20	0
<i><b>Female gonadal function disorders</b></i>		
Anovulatory cycle	64	0
Ovulation delayed	35	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	16	0
Thyroid disorder	10	0
Thyroid mass	2	0
Thyroid pain	11	0
<i><b>Thyroid hyperfunction disorders</b></i>		
Basedow's disease	12	0
Hyperthyroidism	53	0
Primary hyperthyroidism	1	0
Thyrotoxic crisis	5	0
<i><b>Thyroid hypofunction disorders</b></i>		
Autoimmune hypothyroidism	1	0
Hypothyroidic goitre	1	0
Hypothyroidism	41	0
Immune-mediated hypothyroidism	1	0
Myxoedema	1	0
<b>Endocrine disorders SOC TOTAL</b>	<b>347</b>	<b>0</b>

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<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	15	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	8	0
Vitreous detachment	21	0
Vitreous floaters	117	0
<b><i>Colour blindness (incl acquired)</i></b>		
Colour blindness acquired	1	0
Dyschromatopsia	11	0
<b><i>Conjunctival and corneal bleeding and vascular disorders</i></b>		
Conjunctival haemorrhage	51	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
Conjunctival ulcer	1	0
Conjunctivitis allergic	2	0
<b><i>Corneal infections, oedemas and inflammations</i></b>		
Corneal oedema	3	0
Keratitis	7	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	165	0
Excessive eye blinking	6	0
Eyelid function disorder	3	0
Eyelid myokymia	4	0
Eyelid ptosis	50	0
Paralytic lagophthalmos	2	0
<b><i>Glaucomas (excl congenital)</i></b>		
Angle closure glaucoma	2	0
Glaucoma	8	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	3	0
Iridocyclitis	19	0
Iritis	12	0
Uveitis	54	0
Vogt-Koyanagi-Harada disease	1	0
<b><i>Lacrimation disorders</i></b>		
Dry eye	174	0

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Reaction Name	Total	Fatal
<b>Eye disorders</b> Eye disorders cont'd		
Lacrimation increased	163	0
<b><i>Lid bleeding and vascular disorders</i></b>		
Eyelid bleeding	1	0
<b><i>Lid, lash and lacrimal infections, irritations and inflammations</i></b>		
Blepharitis	19	0
Blepharitis allergic	1	0
Chalazion	7	0
Eczema eyelids	9	0
Erythema of eyelid	11	0
Eyelid cyst	7	0
Eyelid irritation	4	0
Eyelid margin crusting	5	0
Eyelid oedema	14	0
Eyelid rash	20	0
Meibomian gland dysfunction	1	0
Swelling of eyelid	145	0
Swollen tear duct	2	0
<b><i>Lid, lash and lacrimal structural disorders</i></b>		
Dacryostenosis acquired	2	0
Dermatochalasis	1	0
Ectropion	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
Lacrimal gland enlargement	1	0
Lagophthalmos	4	0
<b><i>Ocular bleeding and vascular disorders NEC</i></b>		
Eye haematoma	4	0
Eye haemorrhage	37	0
Ocular vascular disorder	2	0
Ophthalmic vein thrombosis	1	0
<b><i>Ocular disorders NEC</i></b>		
Chorioretinal disorder	1	0
Dark circles under eyes	10	0
Eye disorder	41	0
Eye oedema	19	0
Eye pain	1277	0
Eye swelling	641	0
Eye symptom	9	0
Eye ulcer	5	0
Eyelid disorder	17	0
Eyelid pain	15	0
Eyelids pruritus	8	0
Ocular discomfort	34	0
Periorbital oedema	19	0
Periorbital pain	3	0
Periorbital swelling	127	0
Retinal disorder	2	0
Vitreous disorder	1	0
<b><i>Ocular infections, inflammations and associated manifestations</i></b>		

## Case Series Drug Analysis Print

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

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Reaction Name	Total	Fatal
<b>Eye disorders</b> Eye disorders cont'd		
Eye allergy	22	0
Eye discharge	33	0
Eye inflammation	39	0
Eye irritation	105	0
Eye pruritus	279	0
Limbal swelling	4	0
Ocular hyperaemia	260	0
<b>Ocular nerve and muscle disorders</b>		
Binocular eye movement disorder	1	0
Extraocular muscle disorder	1	0
Extraocular muscle paresis	3	0
Eye movement disorder	42	0
Gaze palsy	3	0
Ocular myasthenia	1	0
Ophthalmoplegia	5	0
Strabismus	10	0
<b>Ocular sensation disorders</b>		
Abnormal sensation in eye	22	0
Asthenopia	172	0
Eye paraesthesia	2	0
Eyelid sensory disorder	3	0
Foreign body sensation in eyes	19	0
Hypoaesthesia eye	18	0
Photophobia	519	0
<b>Optic disc abnormalities NEC</b>		
Papilloedema	8	0
<b>Optic nerve bleeding and vascular disorders</b>		
Optic disc haemorrhage	1	0
Optic ischaemic neuropathy	4	0
<b>Orbital infections, inflammations and irritations</b>		
Parophthalmia	1	0
<b>Orbital structural change, deposit and degeneration</b>		
Orbital oedema	2	0
<b>Pupil disorders</b>		
Miosis	2	0
Mydriasis	24	0
Pupil fixed	4	0
Pupillary disorder	1	0
Pupils unequal	14	0
<b>Refractive and accommodative disorders</b>		
Accommodation disorder	1	0
Altered visual depth perception	5	0
Astigmatism	2	0
Hypermetropia	4	0
Myopia	2	0
<b>Retinal bleeding and vascular disorders (excl retinopathy)</b>		
Papillophlebitis	1	0
Retinal artery occlusion	18	0
Retinal artery thrombosis	2	0
Retinal haemorrhage	11	0
Retinal vascular thrombosis	1	0
Retinal vein occlusion	41	0
Retinal vein thrombosis	2	0

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Reaction Name	Total	Fatal
<b>Eye disorders</b> Eye disorders cont'd		
<b><i>Retinal structural change, deposit and degeneration</i></b>		
Age-related macular degeneration	1	0
Epiretinal membrane	1	0
Macular degeneration	4	0
Macular hole	3	0
Macular rupture	1	0
Maculopathy	1	0
Neovascular age-related macular degeneration	3	0
Retinal degeneration	1	0
Retinal detachment	7	0
Retinal tear	3	0
Retinal toxicity	3	0
<b><i>Retinal, choroid and vitreous infections and inflammations</i></b>		
Birdshot chorioretinopathy	2	0
Choroiditis	1	0
Cystoid macular oedema	1	0
Macular oedema	6	0
Retinal oedema	2	0
Retinal vasculitis	3	0
<b><i>Retinopathies NEC</i></b>		
Acute macular neuroretinopathy	3	0
Retinal exudates	2	0
Retinopathy	4	0
<b><i>Scleral infections, irritations and inflammations</i></b>		
Episcleritis	9	0
Scleritis	6	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	2	0
Exophthalmos	4	0
<b><i>Visual colour distortions</i></b>		
Chloropsia	2	0
Chromatopsia	1	0
Cyanopsia	4	0
Erythropsia	2	0
Xanthopsia	1	0
<b><i>Visual disorders NEC</i></b>		
Charles Bonnet syndrome	2	0
Diplopia	180	0
Dysmetropsia	1	0
Glare	1	0
Halo vision	9	0
Heteronymous diplopia	1	0
Metamorphopsia	24	0
Oscillopsia	3	0
Photopsia	158	0
Scintillating scotoma	4	0
Vision blurred	1415	0
Visual brightness	3	0
Visual snow syndrome	8	0
<b><i>Visual field disorders</i></b>		
Visual field defect	37	0



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Reaction Name	Total	Fatal
<b>Eye disorders</b> Eye disorders cont'd		
<i>Visual impairment and blindness (excl colour blindness)</i>		
Amaurosis fugax	4	0
Blindness	155	0
Blindness cortical	1	0
Blindness transient	20	0
Blindness unilateral	19	0
Central vision loss	6	0
Sudden visual loss	4	0
Visual acuity reduced	29	0
Visual acuity reduced transiently	1	0
Visual impairment	450	0
<i>Visual pathway disorders</i>		
Optic nerve disorder	1	0
<b>Eye disorders SOC TOTAL</b>	<b>7808</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Abdominal findings abnormal</i>		
Abdominal mass	2	0
Gastrointestinal sounds abnormal	17	0
<i>Abdominal hernias NEC</i>		
Abdominal hernia	2	0
<i>Abdominal wall conditions NEC</i>		
Abdominal wall haematoma	2	0
<i>Acute and chronic pancreatitis</i>		
Alcoholic pancreatitis	1	0
Autoimmune pancreatitis	1	0
Obstructive pancreatitis	1	0
Pancreatitis	19	0
Pancreatitis acute	17	1
Pancreatitis chronic	1	0
Pancreatitis necrotising	2	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	15	0
<i>Anal and rectal signs and symptoms</i>		
Anal blister	1	0
Anal erythema	1	0
Anal hypoaesthesia	1	0
Anal pruritus	2	0
Anal spasm	1	0
Anorectal discomfort	5	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
Tongue polyp	2	0
<i>Colitis (excl infective)</i>		
Autoimmune colitis	2	0
Colitis	58	1
Colitis ischaemic	1	0
Colitis microscopic	2	0
Colitis ulcerative	78	0
Crohn's disease	49	0
Eosinophilic colitis	1	0
Inflammatory bowel disease	11	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	2	0
Periodontal inflammation	1	0
<i>Dental developmental disorders and anomalies</i>		
Tooth impacted	1	0
<i>Dental disorders NEC</i>		
Loose tooth	5	0

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Malpositioned teeth	2	0
Periodontal disease	1	0
Teeth brittle	3	0
Teething	9	0
Tooth disorder	2	0
Tooth erosion	1	0
Tooth socket haemorrhage	1	0
<b>Dental pain and sensation disorders</b>		
Dental discomfort	7	0
Dental paraesthesia	14	0
Hyperaesthesia teeth	38	0
Toothache	195	0
<b>Dental surface disorders</b>		
Tooth discolouration	10	0
<b>Diaphragmatic hernias</b>		
Hiatus hernia	8	0
<b>Diarrhoea (excl infective)</b>		
Diarrhoea	6032	0
Diarrhoea haemorrhagic	26	0
<b>Diverticula</b>		
Diverticulum	6	0
Diverticulum intestinal	1	0
<b>Duodenal and small intestinal stenosis and obstruction</b>		
Small intestinal obstruction	2	0
<b>Duodenal ulcers and perforation</b>		
Duodenal ulcer haemorrhage	1	0
Duodenal ulcer perforation	3	0
<b>Dyspeptic signs and symptoms</b>		
Dyspepsia	529	0
Epigastric discomfort	15	0
Eructation	62	0
<b>Faecal abnormalities NEC</b>		
Abnormal faeces	23	0
Faecaloma	7	0
Faeces discoloured	63	0
Faeces hard	2	0
Faeces pale	5	0
Faeces soft	12	0
Mucous stools	11	0
<b>Flatulence, bloating and distension</b>		
Abdominal distension	586	0
Aerophagia	3	0
Flatulence	197	0
<b>Gastric and oesophageal haemorrhages</b>		
Gastric haemorrhage	5	1
Mallory-Weiss syndrome	1	0
Oesophageal varices haemorrhage	1	0
<b>Gastric ulcers and perforation</b>		
Gastric ulcer	7	0
<b>Gastritis (excl infective)</b>		
Chronic gastritis	4	0
Gastritis	71	0
Reflux gastritis	8	0

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
<b><i>Gastrointestinal and abdominal pains (excl oral and throat)</i></b>		
Abdominal migraine	2	0
Abdominal pain	1661	0
Abdominal pain lower	148	0
Abdominal pain upper	2761	0
Abdominal rigidity	25	0
Abdominal tenderness	15	0
Gastrointestinal pain	164	0
Oesophageal pain	13	0
<b><i>Gastrointestinal atonic and hypomotility disorders NEC</i></b>		
Constipation	275	0
Duodenogastric reflux	4	0
Gastric dilatation	7	0
Gastrooesophageal reflux disease	190	0
Impaired gastric emptying	10	0
Infrequent bowel movements	3	0
Intestinal dilatation	1	0
Intestinal pseudo-obstruction	2	0
<b><i>Gastrointestinal disorders NEC</i></b>		
Appendicolith	1	0
Appendix disorder	2	0
Food poisoning	7	0
Functional gastrointestinal disorder	11	0
Gastric disorder	10	0
Gastrointestinal disorder	29	0
Stomach mass	4	0
<b><i>Gastrointestinal dyskinetic disorders</i></b>		
Bowel movement irregularity	9	0
Change of bowel habit	13	0
Dyschezia	4	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>		
Appendicitis noninfective	1	0
Duodenitis	1	0
Enteritis	6	0
Eiploic appendagitis	2	0
Gastrointestinal inflammation	4	0
Gastrointestinal tract irritation	1	0
Intestinal angioedema	2	0
<b><i>Gastrointestinal mucosal dystrophies and secretion disorders</i></b>		
Barrett's oesophagus	2	0
Hyperchlorhydria	4	0
<b><i>Gastrointestinal signs and symptoms NEC</i></b>		
Abdominal discomfort	693	0
Abdominal symptom	1	0
Acute abdomen	7	0
Anal incontinence	19	0
Breath odour	22	0
Dysphagia	237	2
Gastrointestinal wall thickening	1	0

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
Gastrointestinal disorders cont'd		
Malignant dysphagia	1	0
Odynophagia	45	0
<b><i>Gastrointestinal spastic and hypermotility disorders</i></b>		
Cardiospasm	1	0
Defaecation urgency	12	0
Frequent bowel movements	30	0
Gastrointestinal hypermotility	1	0
Irritable bowel syndrome	102	0
Oesophageal spasm	5	0
Pylorospasm	1	0
<b><i>Gastrointestinal stenosis and obstruction NEC</i></b>		
Ileus	1	0
Intestinal obstruction	7	0
Neonatal intestinal obstruction	1	0
Volvulus	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	8	2
Mesenteric vein thrombosis	9	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	5	0
Gingival erythema	2	0
Gingival hypertrophy	1	0
Gingival oedema	1	0
Gingival pain	133	0
Gingival pruritus	2	0
Gingival recession	1	0
Gingival swelling	43	0
Gingival ulceration	2	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	11	0
<b><i>Gingival haemorrhages</i></b>		
Gingival bleeding	80	0
<b><i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i></b>		
Gastric varices	1	0
Haemorrhoidal haemorrhage	1	0
Haemorrhoids	35	1
Haemorrhoids thrombosed	1	0
<b><i>Inguinal hernias</i></b>		
Inguinal hernia	1	0
<b><i>Intestinal haemorrhages</i></b>		
Anal haemorrhage	23	1
Intestinal haemorrhage	1	0
Rectal haemorrhage	81	0
Small intestinal haemorrhage	5	0
<b><i>Intestinal ulcers and perforation NEC</i></b>		
Intestinal perforation	5	2

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Large intestinal ulcer	1	0
Large intestinal ulcer haemorrhage	1	0
Large intestine perforation	1	0
<b>Large intestinal stenosis and obstruction</b>		
Large intestinal obstruction	1	1
<b>Malabsorption syndromes</b>		
Bile acid malabsorption	4	0
Coeliac disease	14	0
Malabsorption	1	0
Steatorrhoea	4	0
<b>Nausea and vomiting symptoms</b>		
Discoloured vomit	13	0
Infantile vomiting	7	0
Nausea	15134	0
Regurgitation	1	0
Retching	116	0
Vomiting	5080	1
Vomiting projectile	70	0
<b>Non-mechanical ileus</b>		
Ileus paralytic	2	0
<b>Non-site specific gastrointestinal haemorrhages</b>		
Gastrointestinal haemorrhage	19	1
Haematemesis	38	2
Haematochezia	60	0
Melaena	9	0
Upper gastrointestinal haemorrhage	14	1
<b>Oesophageal stenosis and obstruction</b>		
Oesophageal stenosis	3	0
<b>Oesophagitis (excl infective)</b>		
Eosinophilic oesophagitis	1	0
Oesophagitis	6	0
<b>Oral dryness and saliva altered</b>		
Aptyalism	5	0
Dry mouth	538	0
Lip dry	48	0
Saliva altered	8	0
Salivary hypersecretion	51	0
<b>Oral soft tissue disorders NEC</b>		
Angina bullosa haemorrhagica	1	0
Chapped lips	27	0
Cheilitis	28	0
Enlarged uvula	15	0
Leukoplakia oral	2	0
Lip blister	35	0
Lip disorder	5	0
Oral disorder	21	0
Oral lichen planus	15	0
Oral mucosal hypertrophy	1	0
Oral papule	1	0
Uvulitis	7	0
<b>Oral soft tissue haemorrhages</b>		
Lip haemorrhage	1	0
Mouth haemorrhage	18	0

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Oral blood blister	17	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	7	0
Coating in mouth	1	0
Hypoaesthesia oral	516	0
Lip discolouration	9	0
Lip erythema	4	0
Lip exfoliation	6	0
Lip pain	65	0
Lip pruritus	18	0
Lip scab	1	0
Oral discomfort	88	0
Oral dysaesthesia	1	0
Oral mucosal blistering	17	0
Oral mucosal discolouration	1	0
Oral mucosal eruption	21	0
Oral mucosal erythema	7	0
Oral mucosal exfoliation	10	0
Oral mucosal roughening	3	0
Oral mucosal scab	1	0
Oral pain	182	0
Oral pruritus	24	0
Paraesthesia oral	949	0
Pigmentation lip	1	0
<b><i>Oral soft tissue swelling and oedema</i></b>		
Lip oedema	4	0
Lip swelling	882	0
Mouth swelling	116	0
Oedema mouth	4	0
Palatal oedema	4	0
Palatal swelling	3	0
<b><i>Pancreatic disorders NEC</i></b>		
Pancreatic disorder	1	0
Pancreatic failure	1	0
Pancreatic mass	1	0
<b><i>Peptic ulcers and perforation</i></b>		
Peptic ulcer	1	0
Peptic ulcer haemorrhage	14	0
<b><i>Peritoneal and retroperitoneal disorders</i></b>		
Ascites	2	0
<b><i>Peritoneal and retroperitoneal fibrosis and adhesions</i></b>		
Abdominal adhesions	2	0
<b><i>Peritoneal and retroperitoneal haemorrhages</i></b>		
Haemoperitoneum	1	0
Retroperitoneal haemorrhage	2	1
<b><i>Rectal inflammations NEC</i></b>		
Proctitis	3	0
Proctitis ulcerative	1	0
<b><i>Salivary gland disorders NEC</i></b>		

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Salivary gland disorder	1	0
Salivary gland mucocoele	1	0
Salivary gland pain	13	0
<b><i>Salivary gland enlargements</i></b>		
Parotid gland enlargement	11	0
Salivary gland enlargement	5	0
Submaxillary gland enlargement	8	0
<b><i>Salivary gland infections and inflammations</i></b>		
Noninfective sialoadenitis	2	0
<b><i>Stomatitis and ulceration</i></b>		
Aphthous ulcer	58	0
Lip ulceration	22	0
Mouth ulceration	477	0
Oral mucosa erosion	1	0
Palatal ulcer	1	0
Stomatitis	68	0
<b><i>Tongue disorders</i></b>		
Glossitis	22	0
Hypertrophy of tongue papillae	2	0
Plicated tongue	4	0
Tongue disorder	44	0
Tongue geographic	7	0
Tongue haemorrhage	3	0
Tongue ulceration	34	0
Trichoglossia	4	0
<b><i>Tongue signs and symptoms</i></b>		
Glossodynia	228	0
Scalloped tongue	5	0
Stiff tongue	4	0
Swollen tongue	547	0
Tongue blistering	19	0
Tongue coated	20	0
Tongue discolouration	39	0
Tongue discomfort	45	0
Tongue dry	16	0
Tongue eruption	11	0
Tongue erythema	13	0
Tongue exfoliation	2	0
Tongue movement disturbance	7	0
Tongue oedema	24	0
Tongue pruritus	2	0
Tongue rough	5	0
Tongue spasm	12	0
<b><i>Tooth missing</i></b>		
Tooth loss	6	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>41594</b>	<b>18</b>



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Reaction Name	Total	Fatal
<b>General disorders</b>		
<b><i>Administration site reactions NEC</i></b>		
Administration site bruise	9	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	2	0
Administration site joint pain	1	0
Administration site nerve damage	1	0
Administration site pain	20	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	42	0
Puncture site pain	9	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	10	0
<b><i>Application and instillation site reactions</i></b>		
Application site acne	2	0
Application site bruise	12	0
Application site burn	1	0
Application site dryness	2	0
Application site erythema	18	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	9	0
<b><i>Asthenic conditions</i></b>		
Asthenia	2308	0
Chronic fatigue syndrome	83	0
Decreased activity	10	0
Fatigue	25639	1
Malaise	5766	1

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Sluggishness	19	0
<b>Body temperature altered</b>		
Hyperthermia	7	0
Hyperthermia malignant	1	0
Hypothermia	26	0
Temperature regulation disorder	14	0
<b>Breast complications associated with device</b>		
Breast implant palpable	1	0
Capsular contracture associated with breast implant	2	0
<b>Cardiac complications associated with device</b>		
Prosthetic cardiac valve thrombosis	2	0
<b>Complications associated with device NEC</b>		
Capsular contracture associated with implant	1	0
Complication of device removal	3	0
Injury associated with device	5	0
Medical device pain	1	0
Medical device site swelling	1	0
Phantom shocks	2	0
<b>Death and sudden death</b>		
Brain death	3	2
Cardiac death	3	2
Clinical death	1	1
Death	188	187
Sudden cardiac death	1	1
Sudden death	27	27
<b>Febrile disorders</b>		
Hyperpyrexia	10	0
Pyrexia	16648	0
<b>Feelings and sensations NEC</b>		
Chills	10392	0
Feeling abnormal	1786	0
Feeling cold	1348	0
Feeling drunk	82	0
Feeling hot	1276	0
Feeling jittery	34	0
Feeling of body temperature change	362	0
Feeling of relaxation	3	0
Hangover	84	0
Hunger	51	0
Sensation of blood flow	5	0
Sensation of foreign body	62	0
Sense of oppression	1	0
Temperature intolerance	50	0
Thirst	379	0
Thirst decreased	1	0
<b>Fibrosis NEC</b>		
Fibrosis	1	0
<b>Gait disturbances</b>		
Gait deviation	1	0
Gait disturbance	278	0
Gait inability	106	0
Loss of control of legs	28	0
<b>General signs and symptoms NEC</b>		

## Case Series Drug Analysis Print

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

Report Run Date: 17-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Adhesion	1	0
Chronic disease	1	0
Concomitant disease progression	1	1
Condition aggravated	314	0
Crepitations	5	0
Crying	165	0
Deformity	2	0
Developmental delay	1	0
Discharge	13	0
Disease progression	2	0
Disease recurrence	32	0
Effusion	3	0
Energy increased	27	0
Exercise tolerance decreased	33	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	7	0
High-pitched crying	3	0
Illness	2214	0
Induration	17	0
Influenza like illness	2642	0
Irritability postvaccinal	2	0
Local reaction	92	0
Moaning	4	0
Multiple organ dysfunction syndrome	12	4
Nonspecific reaction	2	0
Organ failure	3	1
Perforation	2	0
Peripheral swelling	4362	0
Physical deconditioning	2	0
Pre-existing condition improved	9	0
Prolapse	1	0
Screaming	24	0
Secretion discharge	24	0
Swelling	3526	0
Swelling face	966	0
Symptom recurrence	1	0
Terminal state	1	0
Tissue irritation	1	0
Tissue rupture	1	0
<b>Healing abnormal NEC</b>		
Impaired healing	6	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 reaction	1	0
Implant site swelling	2	0
Implant site urticaria	1	0
Implant site warmth	3	0

## Case Series Drug Analysis Print

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

Report Run Date: 17-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
<b><i>Inflamations</i></b>		
Foreign body reaction	1	0
Granuloma	1	0
Inflammation	616	0
Papillitis	1	0
Scar inflammation	3	0
Serositis	1	0
Soft tissue inflammation	1	0
Systemic inflammatory response syndrome	6	0
<b><i>Infusion site reactions</i></b>		
Infusion site coldness	1	0
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	5	0
Infusion site pruritus	3	0
Infusion site swelling	2	0
Infusion site urticaria	1	0
Infusion site warmth	2	0
<b><i>Injection site reactions</i></b>		
Injected limb mobility decreased	38	0
Injection site bruising	72	0
Injection site coldness	1	0
Injection site cyst	3	0
Injection site discolouration	5	0
Injection site discomfort	10	0
Injection site eczema	1	0
Injection site erythema	434	0
Injection site extravasation	1	0
Injection site haematoma	1	0
Injection site haemorrhage	9	0
Injection site hypersensitivity	2	0
Injection site hypoaesthesia	16	0
Injection site indentation	10	0
Injection site induration	4	0
Injection site inflammation	49	0
Injection site injury	2	0
Injection site irritation	2	0
Injection site joint discomfort	2	0
Injection site joint erythema	4	0
Injection site joint movement impairment	1	0
Injection site joint pain	15	0
Injection site lymphadenopathy	1	0
Injection site macule	1	0
Injection site mass	635	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	19	0

## Case Series Drug Analysis Print

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

Report Run Date: 17-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Injection site pain	3175	0
Injection site pallor	1	0
Injection site paraesthesia	13	0
Injection site pruritus	243	0
Injection site rash	204	0
Injection site reaction	57	0
Injection site scab	4	0
Injection site scar	4	0
Injection site swelling	347	0
Injection site urticaria	36	0
Injection site vesicles	10	0
Injection site warmth	207	0
<b>Interactions</b>		
Alcohol interaction	5	0
Drug interaction	30	0
Inhibitory drug interaction	3	0
<b>Mass conditions NEC</b>		
Cyst	56	0
Mass	84	0
Nodule	41	0
<b>Mucosal findings abnormal</b>		
Mucosa vesicle	1	0
Mucosal dryness	1	0
Mucosal haemorrhage	10	0
Mucosal inflammation	3	0
Oedema mucosal	2	0
Polyp	6	0
<b>Necrosis NEC</b>		
Fat necrosis	4	0
Necrosis	5	0
<b>Oedema NEC</b>		
Face oedema	35	0
Generalised oedema	6	0
Localised oedema	21	0
Oedema	93	0
Oedema peripheral	99	0
<b>Pain and discomfort NEC</b>		
Axillary pain	4000	0
Breakthrough pain	1	0
Chest discomfort	2010	0
Chest pain	6493	0
Discomfort	554	0
Facial discomfort	21	0
Facial pain	233	0
Inflammatory pain	21	0
Non-cardiac chest pain	34	0
Pain	9870	0
Suprapubic pain	1	0
Tenderness	729	0
Visceral pain	2	0
<b>Therapeutic and nontherapeutic responses</b>		
Adverse drug reaction	29	0
Adverse food reaction	3	0

## Case Series Drug Analysis Print

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

Report Run Date: 17-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Adverse reaction	6	0
Drug ineffective	423	0
Drug intolerance	4	0
Drug resistance	1	0
Immediate post-injection reaction	4	0
Inadequate analgesia	9	0
No reaction on previous exposure to drug	25	0
Product intolerance	1	0
Therapeutic product effect decreased	2	0
Therapeutic product effect delayed	2	0
Therapeutic product effect increased	1	0
Therapeutic product ineffective	2	0
Therapeutic response decreased	2	0
Therapeutic response unexpected	86	0
Therapy non-responder	1	0
Treatment failure	12	0
Vaccination failure	76	0
<b>Trophic disorders</b>		
Abnormal organ growth	1	0
Atrophy	2	0
Calcinosis	2	0
Hyperplasia	1	0
Hypertrophy	1	0
<b>Ulcers NEC</b>		
Ulcer	37	0
Ulcer haemorrhage	1	0
<b>Vaccination site reactions</b>		
Extensive swelling of vaccinated limb	25	0
Shoulder injury related to vaccine administration	62	0
Vaccination site anaesthesia	1	0
Vaccination site bruising	145	0
Vaccination site coldness	4	0
Vaccination site cyst	7	0
Vaccination site dermatitis	2	0
Vaccination site discharge	1	0
Vaccination site discolouration	17	0
Vaccination site discomfort	54	0
Vaccination site dryness	2	0
Vaccination site eczema	1	0
Vaccination site erythema	678	0
Vaccination site granuloma	5	0
Vaccination site haematoma	2	0
Vaccination site haemorrhage	29	0
Vaccination site hypersensitivity	5	0
Vaccination site hypoaesthesia	20	0
Vaccination site induration	79	0
Vaccination site inflammation	65	0
Vaccination site irritation	16	0
Vaccination site joint discomfort	3	0
Vaccination site joint erythema	12	0
Vaccination site joint inflammation	1	0
Vaccination site joint movement impairment	20	0
Vaccination site joint pain	35	0

## Case Series Drug Analysis Print

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

Report Run Date: 17-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
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	330	0
Vaccination site movement impairment	94	0
Vaccination site necrosis	1	0
Vaccination site nerve damage	1	0
Vaccination site nodule	5	0
Vaccination site oedema	3	0
Vaccination site pain	2356	0
Vaccination site papule	2	0
Vaccination site paraesthesia	10	0
Vaccination site phlebitis	1	0
Vaccination site photosensitivity reaction	1	0
Vaccination site pruritus	185	0
Vaccination site rash	153	0
Vaccination site reaction	36	0
Vaccination site scab	3	0
Vaccination site scar	2	0
Vaccination site swelling	645	0
Vaccination site thrombosis	1	0
Vaccination site ulcer	2	0
Vaccination site urticaria	11	0
Vaccination site vesicles	13	0
Vaccination site warmth	299	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	48	0
<b>General disorders SOC TOTAL</b>	<b>118890</b>	<b>230</b>

## Case Series Drug Analysis Print

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

Report Run Date: 17-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i><b>Bile duct infections and inflammations</b></i>		
Biliary colic	19	0
Cholangitis	1	0
<i><b>Cholecystitis and cholelithiasis</b></i>		
Cholecystitis	4	0
Cholecystitis acute	2	0
Cholelithiasis	12	0
<i><b>Cholestasis and jaundice</b></i>		
Cholestasis	2	0
Jaundice	27	0
Jaundice cholestatic	10	0
Ocular icterus	2	0
<i><b>Gallbladder disorders NEC</b></i>		
Gallbladder disorder	3	0
Gallbladder enlargement	1	0
<i><b>Hepatic and hepatobiliary disorders NEC</b></i>		
Hepatic cyst	1	0
Hepatic lesion	1	0
Liver disorder	16	0
<i><b>Hepatic enzymes and function abnormalities</b></i>		
Hepatic function abnormal	7	0
<i><b>Hepatic failure and associated disorders</b></i>		
Acute hepatic failure	2	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	8	0
<i><b>Hepatobiliary signs and symptoms</b></i>		
Hepatic pain	33	0
Hepatomegaly	6	0
Liver tenderness	3	0
<i><b>Hepatocellular damage and hepatitis NEC</b></i>		
Autoimmune hepatitis	13	0
Drug-induced liver injury	3	0
Hepatic steatosis	5	0
Hepatitis	16	0
Hepatitis acute	3	0
Hepatitis toxic	1	0
Hepatotoxicity	1	0
Immune-mediated hepatic disorder	1	0
Liver injury	26	0
<b>Hepatic disorders SOC TOTAL</b>	<b>242</b>	<b>1</b>



## Case Series Drug Analysis Print

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

Report Run Date: 17-Feb-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Acute and chronic sarcoidosis</i>		
Loefgren syndrome	1	0
Sarcoidosis	20	0
<i>Allergic conditions NEC</i>		
Allergic oedema	18	0
Allergy to animal	2	0
Allergy to arthropod bite	7	0
Allergy to arthropod sting	2	0
Allergy to metals	3	0
Allergy to sting	1	0
Hypersensitivity	1132	0
Infusion related hypersensitivity reaction	3	0
Mite allergy	2	0
Multiple allergies	16	0
Serum sickness	3	0
Serum sickness-like reaction	6	0
Type I hypersensitivity	1	0
Type III immune complex mediated reaction	4	0
Type IV hypersensitivity reaction	6	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergic reaction to excipient	6	0
Allergy to chemicals	6	0
Allergy to vaccine	47	0
Contrast media reaction	2	0
Drug hypersensitivity	42	0
Food allergy	44	0
Milk allergy	3	0
Oral allergy syndrome	3	0
Polymers allergy	1	0
Reaction to colouring	1	0
Reaction to excipient	11	0
Reaction to preservatives	5	0
Rubber sensitivity	1	0
Smoke sensitivity	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	557	1
Anaphylactic shock	64	0
Anaphylactoid reaction	26	0
Anaphylactoid shock	4	0
<i>Atopic disorders</i>		
Atopy	3	0
Seasonal allergy	113	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	55	0
<i>Autoinflammatory diseases</i>		
Autoinflammatory disease	1	0
<i>Immune and associated conditions NEC</i>		
Anamnestic reaction	1	0
Bacille Calmette-Guerin scar reactivation	67	0
Cytokine storm	1	0
Decreased immune responsiveness	3	0
Graft versus host disease	2	0
Haemophagocytic lymphohistiocytosis	3	0

## Case Series Drug Analysis Print

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

Report Run Date: 17-Feb-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
Immune system disorders cont'd		
Immune reconstitution inflammatory syndrome	1	0
Immune system disorder	33	0
Immune-mediated adverse reaction	7	0
Immunisation reaction	2	0
Multisystem inflammatory syndrome in children	4	0
Sensitisation	9	0
Systemic immune activation	2	0
<b><i>Immunodeficiency disorders NEC</i></b>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	5	0
Immunosuppression	4	0
<b><i>Transplant rejections</i></b>		
Corneal graft rejection	10	0
Kidney transplant rejection	1	0
Solid organ transplant rejection	1	0
Transplant rejection	2	0
<b>Immune system disorders SOC TOTAL</b>	<b>2382</b>	<b>1</b>

## Case Series Drug Analysis Print

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

Report Run Date: 17-Feb-2022

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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
Anorectal infection	1	0
Appendicitis	46	0
Appendicitis perforated	7	0
Complicated appendicitis	1	0
Diarrhoea infectious	1	0
Diverticulitis	17	0
Dysentery	1	0
Gastric infection	2	0
Gastroenteritis	33	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
Administration site cellulitis	2	0
Arthritis bacterial	4	0
Bacterial colitis	1	0
Bacterial diarrhoea	1	0
Bacterial infection	17	0
Bacterial sepsis	1	0
Bacterial vaginosis	2	0
Cellulitis	201	0
Cellulitis orbital	1	0
Conjunctivitis bacterial	1	0
Ear infection bacterial	1	0
External ear cellulitis	1	0
Folliculitis	19	0
Gangrene	1	0
Gastrointestinal bacterial overgrowth	1	0
Injection site cellulitis	2	0
Meningitis bacterial	3	0
Myocarditis bacterial	1	0
Paronychia	3	0
Perichondritis	3	0
Periorbital cellulitis	3	0
Pneumonia bacterial	2	0
Sinusitis bacterial	2	0
Skin bacterial infection	4	0
Small intestine gangrene	1	0
Tonsillitis bacterial	3	0
Urinary tract infection bacterial	1	0
Vaccination site cellulitis	21	0
Zoonotic bacterial infection	1	1
<b><i>Bartonella infections</i></b>		

## Case Series Drug Analysis Print

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

Report Run Date: 17-Feb-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Infections</b> Infections cont'd		
Cat scratch disease	1	0
<b>Bone and joint infections</b>		
Abscess jaw	1	0
Arthritis infective	2	0
Osteomyelitis	3	0
<b>Bordetella infections</b>		
Pertussis	1	0
<b>Borrelial infections</b>		
Lyme disease	4	0
Relapsing fever	1	0
<b>Breast infections</b>		
Breast abscess	3	0
Mastitis	87	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	71	0
Oral candidiasis	40	0
Respiratory moniliasis	1	0
Skin candida	2	0
Systemic candida	1	0
Urinary tract candidiasis	1	0
Vulvovaginal candidiasis	54	0
<b>Cardiac infections</b>		
Cardiac infection	1	0
Cardiac valve vegetation	1	0
Endocarditis	2	0
Myocarditis infectious	1	0
Pericarditis infective	2	0
<b>Central nervous system and spinal infections</b>		
Brain abscess	2	0
CNS ventriculitis	1	0
Cavernous sinus thrombosis	1	0
Encephalitis	21	0
Encephalomyelitis	1	0
Meningitis	11	0
Meningitis aseptic	3	0
Myelitis	13	0
Subdural abscess	1	0
<b>Clostridia infections</b>		
Clostridium difficile infection	2	0
<b>Coronavirus infections</b>		
Asymptomatic COVID-19	21	0
COVID-19	2405	42
COVID-19 pneumonia	51	14
Coronavirus infection	7	0
Post-acute COVID-19 syndrome	7	0
Severe acute respiratory syndrome	4	0

## Case Series Drug Analysis Print

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

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
Suspected COVID-19	83	4
<b><i>Corynebacteria infections</i></b>		
Diphtheria	2	0
<b><i>Coxiella infections</i></b>		
Q fever	13	0
<b><i>Cytomegaloviral infections</i></b>		
Cytomegalovirus colitis	1	0
Cytomegalovirus infection	2	0
Cytomegalovirus syndrome	1	0
<b><i>Dental and oral soft tissue infections</i></b>		
Abscess oral	6	0
Gingival abscess	1	0
Gingivitis	14	0
Oral infection	1	0
Parotitis	13	0
Pericoronitis	3	0
Periodontitis	1	0
Pulpitis dental	2	0
Sialoadenitis	3	0
Tongue abscess	1	0
Tooth abscess	8	0
Tooth infection	10	0
<b><i>Ear infections</i></b>		
Ear infection	102	0
Labyrinthitis	113	0
Mastoiditis	3	0
Otitis externa	5	0
Otitis media	3	0
Otitis media acute	1	0
Otitis media chronic	5	0
<b><i>Ectoparasitic infestations</i></b>		
Acarodermatitis	6	0
Bed bug infestation	1	0
Demodicidosis	1	0
<b><i>Epstein-Barr viral infections</i></b>		
Epstein-Barr virus infection	5	0
Epstein-Barr virus infection reactivation	2	0
Infectious mononucleosis	29	0
<b><i>Escherichia infections</i></b>		
Escherichia bacteraemia	1	0
Escherichia infection	1	0
<b><i>Eye and eyelid infections</i></b>		
Conjunctivitis	83	0
Eye abscess	1	0
Eye infection	29	0
Eye infection intraocular	1	0
Eyelid boil	2	0
Eyelid infection	2	0
Hordeolum	30	0
Keratouveitis	1	0
Periorbital infection	2	0
<b><i>Female reproductive tract infections</i></b>		
Bartholin's abscess	1	0

## Case Series Drug Analysis Print

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

Report Run Date: 17-Feb-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
Bartholinitis	1	0
Endometritis	3	0
Funisitis	1	0
Pelvic inflammatory disease	2	0
Vaginal infection	3	0
Vulval abscess	1	0
Vulvitis	1	0
<b>Fungal infections NEC</b>		
Fungal infection	21	0
Fungal skin infection	5	0
Myocarditis mycotic	2	0
Onychomycosis	2	0
Oral fungal infection	2	0
Pneumonia fungal	2	0
Severe asthma with fungal sensitisation	2	0
Vulvovaginal mycotic infection	8	0
<b>Hepatitis virus infections</b>		
Hepatitis A	2	0
Hepatitis E	1	0
<b>Hepatobiliary and spleen infections</b>		
Biliary sepsis	3	0
Cholecystitis infective	2	0
Hepatic infection	1	0
<b>Herpes viral infections</b>		
Eczema herpeticum	3	0
Genital herpes	95	0
Genital herpes simplex	6	0
Genital herpes zoster	1	0
Herpes ophthalmic	3	0
Herpes simplex	34	0
Herpes simplex encephalitis	1	1
Herpes simplex reactivation	3	0
Herpes virus infection	13	0
Herpes zoster	1597	0
Herpes zoster disseminated	1	0
Herpes zoster meningoencephalitis	1	0
Herpes zoster oticus	17	0
Herpes zoster reactivation	4	0
Meningitis herpes	1	0
Nasal herpes	5	0
Ophthalmic herpes simplex	3	0
Ophthalmic herpes zoster	5	0
Oral herpes	334	0
Varicella	32	0
Varicella zoster virus infection	4	0
<b>Infections NEC</b>		
Abscess	40	0
Abscess limb	9	0
Abscess soft tissue	1	0
Catheter site infection	1	0
Genital abscess	2	0
Groin abscess	2	0
Groin infection	1	0

## Case Series Drug Analysis Print

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

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Reaction Name	Total	Fatal
<b>Infections</b> Infections cont'd		
Infected bite	3	0
Infected cyst	2	0
Infection	278	0
Infection susceptibility increased	2	0
Injection site abscess	1	0
Injection site infection	5	0
Localised infection	39	0
Lymph gland infection	18	0
Lymph node abscess	7	0
Opportunistic infection	1	0
Pathogen resistance	1	0
Purulent discharge	1	0
Respiratory tract infection	14	0
Superinfection	1	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>		
Nosocomial infection	1	0
Secondary transmission	8	0
Vaccine virus shedding	1	0
<b><i>Influenza viral infections</i></b>		
H1N1 influenza	1	0
Influenza	1783	0
<b><i>Klebsiella infections</i></b>		
Klebsiella infection	1	0
<b><i>Lower respiratory tract and lung infections</i></b>		
Bronchitis	27	0
Infectious pleural effusion	1	0
Lower respiratory tract infection	289	9
Pneumonia	169	15
Pneumonia aspiration	11	7
Sputum purulent	1	0
<b><i>Male reproductive tract infections</i></b>		
Epididymitis	10	0
Orchitis	6	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	8	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
Meningococcal infection	1	0

## Case Series Drug Analysis Print

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

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Reaction Name	Total	Fatal
<b>Infections</b> Infections cont'd		
<b><i>Orthopox viral infections</i></b>		
Smallpox	1	0
Vaccinia virus infection	2	0
<b><i>Plasmodia infections</i></b>		
Malaria	2	0
<b><i>Pneumocystis infections</i></b>		
Pneumocystis jirovecii pneumonia	2	0
<b><i>Pseudomonal infections</i></b>		
Pseudomonas infection	1	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	5	0
<b><i>Salmonella infections</i></b>		
Typhoid fever	1	0
<b><i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i></b>		
Neutropenic sepsis	4	1
Sepsis	64	10
Sepsis syndrome	2	0
Septic rash	2	0
Septic shock	6	1
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	4	0
Injection site pustule	3	0
Nail infection	2	0
Pustule	19	0
Pyoderma	1	0
Rash pustular	12	0
Skin infection	32	0
Subcutaneous abscess	12	0
Sweat gland infection	1	0
Vaccination site pustule	4	0
<b><i>Staphylococcal infections</i></b>		
Furuncle	44	1
Pneumonia staphylococcal	1	0
Staphylococcal abscess	1	0
Staphylococcal infection	5	0
Staphylococcal sepsis	1	0
<b><i>Streptococcal infections</i></b>		
Meningitis pneumococcal	1	0
Pharyngitis streptococcal	8	0



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Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
Pneumonia pneumococcal	1	0
Scarlet fever	1	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	6	0
Tinea capitis	1	0
Tinea infection	1	0
Tinea pedis	3	0
Tinea versicolour	4	0
<b><i>Toxoplasma infections</i></b>		
Toxoplasmosis	1	0
<b><i>Treponema infections</i></b>		
Syphilis	2	0
<b><i>Trypanosomal infections</i></b>		
African trypanosomiasis	4	0
<b><i>Tuberculous infections</i></b>		
Disseminated Bacillus Calmette-Guerin infection	1	0
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	5	0
Chronic sinusitis	3	0
Croup infectious	1	0
Epiglottitis	1	0
Laryngitis	34	0
Nasopharyngitis	1157	1
Peritonsillar abscess	6	0
Pharyngitis	37	0
Rhinitis	54	0
Sinusitis	201	0
Tonsillitis	141	0
Tracheitis	5	0
Tracheostomy infection	1	0
Upper respiratory tract infection	12	0
<b><i>Urinary tract infections</i></b>		
Cystitis	84	0
Kidney infection	55	0
Pyelonephritis	3	0
Urethritis	1	0
Urinary tract infection	218	0
<b><i>Vascular infections</i></b>		
Haematoma infection	1	0
Infected lymphocele	2	0
Infusion site infection	1	0
Lymphangitis	14	0
<b><i>Viral infections NEC</i></b>		
Arthritis viral	1	0
Conjunctivitis viral	2	0

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Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
Ear infection viral	1	0
Encephalitis viral	6	1
Eye infection viral	2	0
Gastroenteritis viral	33	0
Hepatitis viral	3	0
Meningitis viral	9	0
Meningoencephalitis viral	1	0
Oral viral infection	1	0
Pleurisy viral	2	0
Pneumonia viral	4	2
Post viral fatigue syndrome	54	0
Sweating fever	125	0
Vestibular neuronitis	35	0
Viral diarrhoea	2	0
Viral infection	64	0
Viral labyrinthitis	4	0
Viral myocarditis	4	0
Viral pericarditis	3	0
Viral pharyngitis	24	0
Viral rash	68	0
Viral sinusitis	1	0
Viral tonsillitis	2	0
<b>Infections SOC TOTAL</b>	<b>11694</b>	<b>111</b>

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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
Oral mucosal scar	1	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	21	0
<b><i>Anaesthetic and allied procedural complications</i></b>		
Airway complication of anaesthesia	2	0
Delayed recovery from anaesthesia	3	0
Sedation complication	1	0
<b><i>Atmospheric pressure injuries</i></b>		
Barotitis media	1	0
Barotrauma	2	0
Hypobarism	2	0
<b><i>Bone and joint injuries NEC</i></b>		
Bursa injury	3	0
Joint injury	12	0
Meniscus injury	2	0
<b><i>Cardiac and vascular procedural complications</i></b>		
Ischaemic contracture of the left ventricle	1	0
Shunt blood flow excessive	1	0
Vascular pseudoaneurysm	1	0
<b><i>Cardiovascular injuries</i></b>		
Vascular injury	9	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	6	0
Subdural haemorrhage	7	0
Traumatic intracranial haemorrhage	1	1
<b><i>Chemical injuries</i></b>		
Chemical burn	1	0
Chemical burn of skin	9	0
Chemical cystitis	2	0
<b><i>Chest and respiratory tract injuries NEC</i></b>		
Bronchial injury	1	0
Chest crushing	15	0
Foreign body in throat	1	0
Traumatic lung injury	1	0
<b><i>Conditions caused by cold</i></b>		
Chillblains	73	0
Cold shock response	1	0

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Reaction Name	Total	Fatal
<b>Injuries</b> <span style="float: right;">Injuries cont'd</span>		
Frostbite	1	0
<b>Cranial nerve injuries</b>		
IIIrd nerve injury	1	0
Vth nerve injury	1	0
<b>Ear injuries NEC</b>		
Deafness traumatic	1	0
Ear injury	1	0
<b>Exposures associated with pregnancy, delivery and lactation</b>		
Exposure during pregnancy	10	0
Exposure via breast milk	157	0
Foetal exposure during pregnancy	67	0
Foetal exposure timing unspecified	1	0
Maternal exposure before pregnancy	27	0
Maternal exposure during breast feeding	1974	0
Maternal exposure during delivery	1	0
Maternal exposure during pregnancy	1066	0
Maternal exposure timing unspecified	14	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	16	0
Eye injury	29	0
Foreign body in eye	4	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>		
Fracture	3	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	11	0
Procedural vomiting	2	0
<b>Heat injuries (excl thermal burns)</b>		
Heat cramps	2	0
Heat exhaustion	3	0
Heat illness	2	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>		

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Reaction Name	Total	Fatal
<b>Injuries</b>		
Injuries cont'd		
Ankle fracture	1	0
Atypical femur fracture	1	0
Clavicle fracture	28	0
Femoral neck fracture	1	0
Femur fracture	1	0
Fibula fracture	1	0
Hip fracture	2	0
Tibia fracture	1	0
Upper limb fracture	1	0
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	27	0
Prescription drug used without a prescription	3	0
Product use complaint	2	0
Product use issue	33	0
Vaccination error	6	0
Wrong dose	4	0
Wrong drug	11	0
Wrong schedule	1	0
Wrong technique in product usage process	7	0
<b>Muscle, tendon and ligament injuries</b>		
Epicondylitis	24	0
Ligament injury	2	0
Ligament sprain	10	0
Mallet finger	1	0
Muscle hernia	1	0
Muscle injury	38	0
Muscle rupture	10	0
Muscle strain	37	0
Post-traumatic neck syndrome	2	0
Tendon injury	7	0
Tendon rupture	26	0
<b>Musculoskeletal procedural complications</b>		
Periprosthetic osteolysis	1	0
Post laminectomy syndrome	1	0
<b>Nerve injuries NEC</b>		
Nerve injury	112	0
<b>Neurological and psychiatric procedural complications</b>		
Post lumbar puncture syndrome	1	0
Post procedural stroke	1	0
Procedural dizziness	12	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	10	0
Arthropod sting	6	0
Bite	1	0
Bone contusion	1	0
Crush injury	1	0

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Reaction Name	Total	Fatal
<b>Injuries</b> <span style="float: right;">Injuries cont'd</span>		
Electric shock	20	0
Fall	207	0
Foreign body	5	0
Injury	14	0
Multiple injuries	2	0
Nervous system injury	2	0
Post concussion syndrome	2	0
Traumatic haematoma	1	0
Wound	7	0
Wound complication	12	0
Wound haematoma	1	0
Wound haemorrhage	3	0
Wound secretion	6	0
<b>Non-site specific procedural complications</b>		
Administration related reaction	2	0
Anastomotic leak	1	0
Incision site pain	3	0
Infusion related reaction	8	0
Injection related reaction	66	0
Post procedural complication	5	0
Post procedural erythema	1	0
Post procedural inflammation	1	0
Post procedural pruritus	1	0
Procedural pain	4	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	437	0
<b>Overdoses NEC</b>		
Intentional overdose	1	0
Overdose	52	0
<b>Pathways and sources of exposure</b>		
Exposure via contaminated device	1	0
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
Radial nerve injury	2	0
Sciatic nerve injury	2	0
Ulnar nerve injury	4	0
<b>Poisoning and toxicity</b>		
Alcohol poisoning	1	0
Poisoning	14	0
Toxicity to various agents	4	0
<b>Product administration errors and issues</b>		
Accidental overdose	8	0
Contraindicated product administered	2	0
Duplicate therapy error	1	0
Expired product administered	14	0

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Reaction Name	Total	Fatal
<b>Injuries</b>		
Injuries cont'd		
Inappropriate schedule of product administration	691	0
Incomplete course of vaccination	2	0
Incorrect dose administered	57	0
Incorrect drug administration rate	1	0
Incorrect product formulation administered	2	0
Incorrect route of product administration	7	0
Lack of vaccination site rotation	1	0
Poor quality product administered	3	0
Product administered at inappropriate site	24	0
Product administered to patient of inappropriate age	1	0
Product administration error	13	0
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	5	0
Product packaging confusion	1	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	23	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>		
Breast injury	1	0
Cervix injury	1	0
Penile contusion	1	0
Penis injury	2	0
Uterine rupture	1	0
<b>Reproductive tract and breast procedural complications</b>		
Failed in vitro fertilisation	1	0
<b>Site specific injuries NEC</b>		
Back injury	3	0
Face crushing	4	0
Face injury	1	0
Head injury	36	0
Limb crushing injury	4	0
Limb injury	192	0
Nasal injury	2	0
Neck crushing	1	0
Neck injury	1	0
Pharyngeal contusion	1	0

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Reaction Name	Total	Fatal
<b>Injuries</b>		
Injuries cont'd		
<b>Site specific procedural complications NEC</b>		
Axillary web syndrome	3	0
<b>Skin injuries NEC</b>		
Contusion	1369	0
Hair injury	1	0
Nail avulsion	1	0
Scar	33	0
Scratch	7	0
Skin abrasion	7	0
Skin injury	4	0
Skin laceration	4	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
<b>Skull fractures, facial bone fractures and dislocations</b>		
Facial bones fracture	1	0
Fractured skull depressed	1	0
<b>Spinal cord injuries NEC</b>		
Spinal cord injury cervical	1	0
<b>Spinal fractures and dislocations</b>		
Spinal compression fracture	1	0
Spinal fracture	4	0
<b>Stoma complications</b>		
Gastrointestinal stoma complication	2	0
Stoma site discharge	1	0
Stoma site extravasation	1	0
Stoma site haemorrhage	1	0
<b>Thermal burns</b>		
Airway burns	1	0
Burn oesophageal	4	0
Burn of internal organs	4	0
Burn oral cavity	5	0
Burns second degree	3	0
Burns third degree	1	0
Cold burn	1	0
Thermal burn	26	0
Thermal burns of eye	17	0
<b>Underdoses NEC</b>		
Underdose	6	0
<b>Vaccination related complications</b>		
Adverse event following immunisation	1	0
Post vaccination syndrome	1	0
Vaccination complication	54	0
<b>Injuries SOC TOTAL</b>	<b>7726</b>	<b>1</b>



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Reaction Name	Total	Fatal
<b>Investigations</b>		
<b><i>Adrenal cortex tests</i></b>		
Cortisol decreased	5	0
<b><i>Adrenal medulla tests</i></b>		
Epinephrine	1	0
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
Weber tuning fork test abnormal	1	0
<b><i>Autoimmunity analyses</i></b>		
Antineutrophil cytoplasmic antibody positive	1	0
Antinuclear antibody	3	0
Antinuclear antibody increased	1	0
Antinuclear antibody positive	1	0
Beta-2 glycoprotein antibody positive	1	0
Cardiolipin antibody positive	1	0
Rheumatoid factor	3	0
Rheumatoid factor increased	1	0
Rheumatoid factor positive	1	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	7	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	11	0
Oxygen saturation abnormal	2	0
Oxygen saturation decreased	95	0
PO2 decreased	1	0
Venous oxygen saturation decreased	1	0
<b><i>Blood grouping and cross-matching analyses</i></b>		
Rhesus antigen positive	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	12	0
Blood glucose abnormal	15	0
Blood glucose decreased	38	0
Blood glucose fluctuation	17	0

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Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Blood glucose increased	109	0
Blood glucose normal	1	0
Glycosylated haemoglobin increased	1	0
<b>Cardiac auscultatory investigations</b>		
Cardiac murmur	46	0
Heart sounds	9	0
Heart sounds abnormal	6	0
<b>Cardiac function diagnostic procedures</b>		
Cardiac monitoring	1	0
Cardiac output	1	0
Central venous pressure	1	0
Echocardiogram	1	0
Ejection fraction decreased	3	0
Myocardial strain imaging	2	0
Right atrial volume abnormal	1	0
Stroke volume decreased	1	0
<b>Cardiac imaging procedures</b>		
Catheterisation cardiac	1	0
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	3	0
<b>Central nervous system imaging procedures</b>		
Computerised tomogram head	10	0
Magnetic resonance imaging head	12	0
Magnetic resonance imaging head abnormal	2	0
<b>Cerebrospinal fluid tests (excl microbiology)</b>		
CSF pressure	1	0
CSF protein increased	1	0
<b>Chemistry analyses NEC</b>		
Histamine abnormal	1	0
Histamine level	1	0
Histamine level increased	2	0
Inflammatory marker decreased	1	0
Inflammatory marker increased	5	0
Inflammatory marker test	1	0
Renin	1	0
<b>Cholesterol analyses</b>		
Blood cholesterol increased	13	0
Remnant-like lipoprotein particles	4	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	2	0
Bleeding time prolonged	11	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

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Reaction Name	Total	Fatal
<b>Investigations</b>		
Investigations cont'd		
Fibrin D dimer increased	25	0
International normalised ratio abnormal	8	0
International normalised ratio decreased	22	0
International normalised ratio fluctuation	3	0
International normalised ratio increased	53	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
Electrocardiogram QRS complex prolonged	1	0
Electrocardiogram QT prolonged	11	0
Electrocardiogram ST segment depression	2	0
Electrocardiogram ST segment elevation	11	0
Electrocardiogram ST-T segment abnormal	2	0
Electrocardiogram T wave inversion	6	0
Electrocardiogram abnormal	23	0
Electrocardiogram change	1	0
Electrocardiogram normal	3	0
Electrocardiogram repolarisation abnormality	1	0
QRS axis abnormal	1	0
<b>Endocrine analyses and imaging NEC</b>		
Hormone level abnormal	83	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
Semen volume increased	1	0
Sperm concentration	2	0
Sperm concentration decreased	2	0
Spermatozoa abnormal	1	0
<b>Foetal and neonatal diagnostic procedures</b>		
Foetal heart rate abnormal	5	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	4	0
<b>Gastrointestinal, pancreatic and APUD hormone analyses</b>		
Blood insulin	2	0
Blood insulin decreased	1	0
<b>Gene analyses</b>		
EGFR status assay	1	0
<b>Haematological analyses NEC</b>		
Blood viscosity abnormal	1	0

## Case Series Drug Analysis Print

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

Report Run Date: 17-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Blood viscosity decreased	1	0
Blood viscosity increased	2	0
Plasma viscosity	1	0
Plasma viscosity abnormal	1	0
Red blood cell sedimentation rate increased	8	0
<b><i>Heart rate and pulse investigations</i></b>		
Carotid pulse	1	0
Heart rate	573	0
Heart rate abnormal	74	0
Heart rate decreased	102	0
Heart rate increased	1160	0
Heart rate irregular	280	0
Heart rate normal	1	0
Heart rate variability decreased	1	0
Maximum heart rate	3	0
Maximum heart rate increased	2	0
Pulse abnormal	23	0
Pulse absent	1	0
Pulse pressure increased	3	0
Radial pulse abnormal	1	0
Sinus rhythm	8	0
<b><i>Hepatobiliary imaging procedures</i></b>		
Liver scan	1	0
<b><i>Imaging procedures NEC</i></b>		
Computerised tomogram	4	0
Magnetic resonance imaging	5	0
Magnetic resonance imaging abnormal	1	0
Scan	2	0
X-ray	2	0
<b><i>Immune response protein analyses NEC</i></b>		
Cytokine test	1	0
<b><i>Immunoglobulin analyses</i></b>		
Blood immunoglobulin E increased	2	0
Blood immunoglobulin G increased	1	0
Blood immunoglobulin M	1	0
Blood immunoglobulin M increased	2	0
<b><i>Immunology analyses NEC</i></b>		
Antibody test	4	0
Antibody test positive	1	0
Immunology test	13	0
<b><i>Immunology skin tests NEC</i></b>		
Allergy alert test	1	0
Skin test positive	2	0
<b><i>Investigations NEC</i></b>		
Blood test	28	0
Blood test abnormal	48	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	1	0
Systemic lupus erythematosus disease activity index increased	1	0
<b><i>Liver function analyses</i></b>		

## Case Series Drug Analysis Print

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

Report Run Date: 17-Feb-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Investigations</b>		
Investigations cont'd		
Alanine aminotransferase increased	28	0
Aspartate aminotransferase	1	0
Aspartate aminotransferase abnormal	1	0
Aspartate aminotransferase increased	2	0
Blood bilirubin increased	6	0
Gamma-glutamyltransferase increased	5	0
Hepatic enzyme increased	10	0
Liver function test	1	0
Liver function test abnormal	33	0
Liver function test increased	30	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
N-terminal prohormone brain natriuretic peptide increased	1	0
Ubiquinone	1	0
Urine ketone body	1	0
Urine ketone body present	1	0
<b>Microbiology and serology tests NEC</b>		
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	2	0
Blood iron decreased	11	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	11	0
Serum ferritin	1	0
Serum ferritin decreased	5	0
Serum ferritin increased	1	0
Sweat test	2	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	1	0
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

## Case Series Drug Analysis Print

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

Report Run Date: 17-Feb-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Hoover's sign of leg paresis	1	0
Joint position sense decreased	1	0
Lumbar puncture	6	0
Magnetic resonance neurography	1	0
Nerve conduction studies	1	0
Pain threshold decreased	1	0
Sensory level	2	0
Temperature perception test abnormal	1	0
Temperature perception test increased	1	0
<b><i>Ophthalmic function diagnostic procedures</i></b>		
Corneal reflex decreased	1	0
Intraocular pressure increased	8	0
Intraocular pressure test	3	0
Pupil dilation procedure	1	0
Visual acuity tests	1	0
<b><i>Physical examination procedures and organ system status</i></b>		
Body temperature	290	0
Body temperature abnormal	53	0
Body temperature decreased	45	0
Body temperature fluctuation	66	0
Body temperature increased	504	0
Body temperature normal	1	0
Breath sounds abnormal	2	0
General physical condition abnormal	1	0
Grip strength	3	0
Grip strength decreased	25	0
Gynaecological examination	1	0
Head lag	8	0
Intelligence test	1	0
Lymph node palpable	45	0
Male genital examination abnormal	1	0
Menstruation normal	4	0
Muscle strength abnormal	4	0
Ophthalmological examination	3	0
Orthopaedic examination	1	0
Palpatory finding abnormal	2	0
Product residue present	2	0
Psoriasis area severity index decreased	2	0
Psoriasis area severity index increased	1	0
Respiratory rate	9	0
Respiratory rate decreased	27	0
Respiratory rate increased	46	0
Skin temperature	44	0
Temperature difference of extremities	13	0
Weight	1	0
Weight abnormal	1	0
Weight decreased	128	0
Weight increased	51	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

## Case Series Drug Analysis Print

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

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Blood prolactin increased	4	0
Blood thyroid stimulating hormone decreased	1	0
Blood thyroid stimulating hormone increased	10	0
<b>Platelet analyses</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	80	0
Platelet count increased	6	0
<b>Protein analyses NEC</b>		
Alpha 1 globulin decreased	1	0
Alpha 2 globulin decreased	1	0
C-reactive protein increased	29	0
<b>Red blood cell analyses</b>		
Haematocrit	1	0
Haematocrit decreased	1	0
Haematocrit increased	1	0
Haemoglobin decreased	16	0
Haemoglobin increased	2	0
Red blood cell count decreased	1	0
Red blood cell rouleaux formation present	1	0
<b>Renal function analyses</b>		
Blood creatinine	1	0
Blood creatinine decreased	1	0
Blood creatinine increased	5	0
Glomerular filtration rate decreased	4	0
Glomerular filtration rate increased	1	0
<b>Reproductive hormone analyses</b>		
Blood oestrogen	2	0
Blood oestrogen decreased	2	0
Blood testosterone decreased	1	0
Blood testosterone increased	2	0
False negative pregnancy test	9	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
Progesterone decreased	1	0
<b>Reproductive organ and breast histopathology procedures</b>		
Biopsy breast	2	0
Biopsy endometrium	1	0
Smear cervix	3	0
<b>Reproductive organ and breast imaging procedures</b>		
Breast scan	1	0
Hysteroscopy	2	0
<b>Respiratory and pulmonary function diagnostic procedures</b>		
Airway peak pressure increased	1	0
Forced expiratory volume increased	3	0
Fractional exhaled nitric oxide normal	1	0
Maximal voluntary ventilation	2	0
Peak expiratory flow rate	2	0

## Case Series Drug Analysis Print

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

Report Run Date: 17-Feb-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Peak expiratory flow rate decreased	6	0
Pulmonary function test	3	0
Total lung capacity decreased	4	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	2	0
Ventilation/perfusion scan	1	0
<b><i>Skeletal and cardiac muscle analyses</i></b>		
Blood creatine phosphokinase increased	12	0
Muscle enzyme	1	0
Myocardial necrosis marker	1	0
Myocardial necrosis marker increased	3	0
Troponin I increased	2	0
Troponin T increased	2	0
Troponin increased	23	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
Blood alkaline phosphatase increased	5	0
Blood lactate dehydrogenase increased	1	0
Enzyme level increased	1	0
<b><i>Toxicology laboratory analyses</i></b>		
Blood caffeine decreased	1	0
Blood lead	1	0
Drug screen positive	2	0
Opiates	1	0
<b><i>Urinalysis NEC</i></b>		
Blood urine	18	0
Blood urine present	74	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



## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Urine leukocyte esterase positive	1	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	14	0
Urine output decreased	14	0
Urine output increased	7	0
<b>Urinary tract histopathology procedures</b>		
Urine cytology	1	0
<b>Urinary tract imaging procedures</b>		
Bladder scan	1	0
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	11	0
Blood pressure ambulatory increased	1	0
Blood pressure decreased	88	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	291	0
Blood pressure measurement	49	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 antibody 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
SARS-CoV-2 antibody test positive	6	0
SARS-CoV-2 test	35	0
SARS-CoV-2 test false negative	2	0
SARS-CoV-2 test false positive	4	0
SARS-CoV-2 test negative	10	0
SARS-CoV-2 test positive	109	0
Viral load	2	0
Viral test	4	0
Viral test positive	1	0
<b>Vitamin analyses</b>		
Blood folate decreased	7	0
Vitamin B12	1	0
Vitamin B12 abnormal	2	0

## Case Series Drug Analysis Print

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

Report Run Date: 17-Feb-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Vitamin B12 decreased	2	0
Vitamin D	4	0
Vitamin D decreased	3	0
<b><i>Water and electrolyte analyses NEC</i></b>		
Urine osmolarity	1	0
Volume blood	1	0
<b><i>White blood cell analyses</i></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	2	0
Neutrophil count	4	0
Neutrophil count decreased	11	0
Neutrophil count increased	4	0
White blood cell count	4	0
White blood cell count decreased	14	0
White blood cell count increased	12	0
<b>Investigations SOC TOTAL</b>	<b>6165</b>	<b>3</b>

## Case Series Drug Analysis Print

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

Report Run Date: 17-Feb-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Appetite disorder	21	0
Decreased appetite	1481	0
Diet refusal	1	0
Eating disorder symptom	3	0
Food craving	13	0
Food refusal	16	0
Hyperphagia	15	0
Hypophagia	18	0
Increased appetite	36	0
Salt craving	2	0
<i><b>Calcium metabolism disorders</b></i>		
Hypocalcaemia	3	0
Tetany	3	0
<i><b>Copper metabolism disorders</b></i>		
Copper deficiency	1	0
<i><b>Diabetes mellitus (incl subtypes)</b></i>		
Diabetes mellitus	54	0
Diabetes mellitus inadequate control	17	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	5	0
<i><b>Diabetic complications NEC</b></i>		
Diabetic complication	2	0
Diabetic ketoacidosis	12	0
Diabetic ketosis	1	0
<i><b>Disorders of purine metabolism</b></i>		
Gout	106	0
<i><b>Electrolyte imbalance NEC</b></i>		
Electrolyte imbalance	1	0
Fluid imbalance	2	0
<i><b>Fat soluble vitamin deficiencies and disorders</b></i>		
Vitamin D deficiency	9	0
<i><b>Fluid intake decreased</b></i>		
Fluid intake reduced	2	0
<i><b>Fluid intake increased</b></i>		
Polydipsia	7	0
<i><b>Food malabsorption and intolerance syndromes (excl sugar intolerance)</b></i>		
Alcohol intolerance	8	0
Breast milk substitute intolerance	1	0
Dairy intolerance	3	0
Food intolerance	19	0
Gluten sensitivity	7	0
Histamine intolerance	4	0
<i><b>General nutritional disorders NEC</b></i>		
Abnormal loss of weight	36	0
Abnormal weight gain	20	0
Cachexia	1	0
Feeding disorder	107	0
Food aversion	12	0
Malnutrition	3	0

## Case Series Drug Analysis Print

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

Report Run Date: 17-Feb-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Metabolic disorders</b> <small>Metabolic disorders cont'd</small>		
Neonatal insufficient breast milk syndrome	7	0
Obesity	1	0
Overweight	1	0
Poor feeding infant	16	0
Weight loss poor	3	0
<b>Hyperglycaemic conditions NEC</b>		
Glucose tolerance impaired	1	0
Hyperglycaemia	68	0
Insulin resistance	5	0
<b>Hyperlipidaemias NEC</b>		
Hyperlipidaemia	1	0
<b>Hypoglycaemic conditions NEC</b>		
Glycopenia	1	0
Hypoglycaemia	80	0
Hypoglycaemia unawareness	1	0
Postprandial hypoglycaemia	2	0
<b>Iron deficiencies</b>		
Iron deficiency	13	0
<b>Iron excess</b>		
Haemochromatosis	2	0
Iron overload	1	0
<b>Lipid metabolism and deposit disorders NEC</b>		
Body fat disorder	1	0
<b>Magnesium metabolism disorders</b>		
Hypomagnesaemia	1	0
Magnesium deficiency	1	0
<b>Metabolic acidoses (excl diabetic acidoses)</b>		
Ketoacidosis	6	1
Lactic acidosis	3	0
Metabolic acidosis	4	0
<b>Metabolic disorders NEC</b>		
Hypercarotinaemia	1	0
Hypercatabolism	1	0
Metabolic disorder	1	0
<b>Mixed acid-base disorders</b>		
Acidosis	4	0
<b>Phosphorus metabolism disorders</b>		
Hypophosphataemia	1	0
<b>Potassium imbalance</b>		
Hyperkalaemia	6	0
Hypokalaemia	5	0
Hypokalaemic syndrome	1	0
<b>Sodium imbalance</b>		
Hypernatraemia	1	1
Hyponatraemia	12	0
Hyponatraemic syndrome	3	0
Salt intoxication	1	0
<b>Sugar intolerance (excl glucose intolerance)</b>		
Lactose intolerance	5	0
<b>Total fluid volume decreased</b>		
Dehydration	235	0
<b>Total fluid volume increased</b>		
Fluid retention	65	0

## Case Series Drug Analysis Print

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

Report Run Date: 17-Feb-2022

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b> Metabolic disorders cont'd		
Hypervolaemia	5	0
<b>Vitamin deficiencies NEC</b>		
Hypovitaminosis	6	0
<b>Water soluble vitamin deficiencies</b>		
Folate deficiency	7	0
Vitamin B complex deficiency	1	0
Vitamin B12 deficiency	6	0
<b>Metabolic disorders SOC TOTAL</b>	<b>2659</b>	<b>3</b>

## Case Series Drug Analysis Print

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

Report Run Date: 17-Feb-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i><b>Arthropathies NEC</b></i>		
Arthritis	387	0
Arthropathy	33	0
Autoimmune arthritis	9	0
Haemarthrosis	5	0
Joint microhaemorrhage	1	0
Palindromic rheumatism	2	0
Polyarthritis	16	0
Rheumatic fever	2	0
Sacroiliitis	6	0
Seronegative arthritis	3	0
<i><b>Bone disorders NEC</b></i>		
Bone cyst	1	0
Exostosis	1	0
Jaw disorder	4	0
Medial tibial stress syndrome	6	0
Osteitis	9	0
Osteonecrosis	1	0
Osteonecrosis of jaw	3	0
Spinal disorder	1	0
<i><b>Bone related signs and symptoms</b></i>		
Bone pain	447	0
Bone swelling	10	0
Coccydynia	4	0
Metatarsalgia	1	0
Pain in jaw	425	0
Pubic pain	2	0
Spinal pain	96	0
<i><b>Bursal disorders</b></i>		
Bursitis	99	0
<i><b>Cartilage disorders</b></i>		
Chondritis	1	0
Costochondritis	136	0
Osteochondritis	1	0
Polychondritis	3	0
<i><b>Connective tissue disorders NEC</b></i>		
Connective tissue disorder	2	0
Polymyalgia rheumatica	80	0
Reynold's syndrome	2	0
Scleroderma	1	0
Sjogren's syndrome	7	0
Systemic scleroderma	1	0
<i><b>Crystal arthropathic disorders</b></i>		
Chondrocalcinosis pyrophosphate	3	0
Crystal arthropathy	2	0
Gouty arthritis	2	0
<i><b>Epiphyseal disorders</b></i>		
Epiphyses premature fusion	1	0
<i><b>Extremity deformities</b></i>		
Bone deformity	1	0
Finger deformity	2	0
Foot deformity	3	0
Hand deformity	4	0

## Case Series Drug Analysis Print

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

Report Run Date: 17-Feb-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
Muscle & tissue disorders cont'd		
Knee deformity	1	0
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	1	0
Joint ankylosis	1	0
Joint deposit	1	0
Joint destruction	1	0
Joint instability	2	0
Joint laxity	3	0
Joint lock	34	0
Ligament laxity	1	0
Patellofemoral pain syndrome	2	0
Periarthritis	242	0
Rotator cuff syndrome	40	0
Temporomandibular joint syndrome	14	0
<b>Joint related signs and symptoms</b>		
Arthralgia	10347	0
Jaw clicking	7	0
Joint effusion	16	0
Joint noise	43	0
Joint range of motion decreased	34	0
Joint stiffness	294	0
Joint swelling	648	0
Joint vibration	4	0
Joint warmth	17	0
Loose body in joint	1	0
<b>Ligament disorders</b>		
Ligament pain	4	0
Ligamentitis	1	0
Symphysiolysis	1	0
<b>Lupus erythematosus (incl subtypes)</b>		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	29	0
<b>Metabolic bone disorders</b>		
Osteopenia	4	0
Osteoporosis	7	0
<b>Muscle infections and inflammations</b>		
Antisynthetase syndrome	3	0
Immune-mediated myositis	2	0
Myositis	51	0
Polymyositis	9	0
<b>Muscle pains</b>		
Fibromyalgia	141	0
Myalgia	11685	0
Myalgia intercostal	2	0
Myofascial pain syndrome	12	0

## Case Series Drug Analysis Print

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

Report Run Date: 17-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Muscle &amp; tissue disorders cont'd</i>		
<b><i>Muscle related signs and symptoms NEC</i></b>		
Haematoma muscle	1	0
Muscle atrophy	25	0
Muscle discomfort	8	0
Muscle disorder	10	0
Muscle fatigue	395	0
Muscle haemorrhage	1	0
Muscle mass	5	0
Muscle oedema	5	0
Muscle spasms	2317	0
Muscle swelling	43	0
Muscle tightness	99	0
Muscle twitching	550	0
<b><i>Muscle tone abnormalities</i></b>		
Muscle rigidity	20	0
Nuchal rigidity	13	0
Torticollis	7	0
Trismus	40	0
<b><i>Muscle weakness conditions</i></b>		
Muscular weakness	1123	0
<b><i>Musculoskeletal and connective tissue conditions NEC</i></b>		
Back disorder	4	0
Chest wall mass	1	0
Growth disorder	2	0
Limb mass	24	0
Mandibular mass	3	0
Mastication disorder	7	0
Mobility decreased	142	0
Muscle contracture	1	0
Musculoskeletal disorder	13	0
Musculoskeletal stiffness	1482	0
Pelvic misalignment	1	0
Posture abnormal	2	0
Sacroiliac joint dysfunction	1	0
Weight bearing difficulty	5	0
<b><i>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</i></b>		
Facial asymmetry	1	0
Head deformity	2	0
Nose deformity	1	0
<b><i>Musculoskeletal and connective tissue infections and inflammations NEC</i></b>		
Connective tissue inflammation	1	0
Dactylitis	3	0
Dupuytren's contracture	1	0
Fasciitis	1	0
Plantar fasciitis	14	0
<b><i>Musculoskeletal and connective tissue pain and discomfort</i></b>		
Back pain	2812	0
Flank pain	86	0
Growing pains	1	0
Limb discomfort	1654	0
Musculoskeletal chest pain	304	0
Musculoskeletal discomfort	125	0



## Case Series Drug Analysis Print

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

Report Run Date: 17-Feb-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
Musculoskeletal pain	136	0
Neck pain	2200	0
Pain in extremity	14360	1
Rheumatic disorder	15	0
Sacral pain	4	0
<b>Myopathies</b>		
Mitochondrial myopathy acquired	1	0
Myopathy	7	0
Rhabdomyolysis	14	0
<b>Osteoarthropathies</b>		
Nodal osteoarthritis	1	0
Osteoarthritis	63	0
Spinal osteoarthritis	2	0
<b>Psoriatic arthropathies</b>		
Psoriatic arthropathy	22	0
<b>Rheumatoid arthropathies</b>		
Juvenile idiopathic arthritis	1	0
Rheumatoid arthritis	136	0
Rheumatoid nodule	1	0
Still's disease	2	0
<b>Soft tissue disorders NEC</b>		
Axillary mass	312	0
Fistula	1	0
Fluctuance	1	0
Groin pain	126	0
Neck mass	45	0
Purple glove syndrome	1	0
Soft tissue disorder	3	0
Soft tissue swelling	7	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	10	0
Arthritis reactive	71	0
Spondylitis	4	0
Spondyloarthropathy	1	0
<b>Synovial disorders</b>		
Synovial cyst	23	0
Synovitis	12	0
<b>Tendon disorders</b>		
Enthesopathy	3	0
Posterior tibial tendon dysfunction	1	0
Tendon disorder	6	0
Tendon pain	27	0
Tendonitis	59	0
Tenosynovitis	4	0
Tenosynovitis stenosans	2	0
Trigger finger	34	0
<b>Trunk deformities</b>		

# Case Series Drug Analysis Print

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

Report Run Date: 17-Feb-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
Muscle & tissue disorders cont'd		
Deformity thorax	1	0
Drooping shoulder syndrome	2	0
Shoulder deformity	4	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>54632</b>	<b>1</b>

## Case Series Drug Analysis Print

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

Report Run Date: 17-Feb-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i>Adrenal neoplasms malignant</i>		
Adrenal gland cancer	1	0
<i>Angioimmunoblastic T-cell lymphomas</i>		
Angioimmunoblastic T-cell lymphoma	1	0
<i>B-cell lymphomas NEC</i>		
B-cell lymphoma	2	1
Follicular lymphoma	4	0
<i>Bone neoplasms malignant (excl sarcomas)</i>		
Bone cancer	1	1
<i>Bone neoplasms unspecified malignancy</i>		
Bone neoplasm	1	0
<i>Breast and nipple neoplasms benign</i>		
Benign breast neoplasm	3	0
Fibroadenoma of breast	2	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	42	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
<i>Cardiovascular neoplasms benign</i>		
Haemangioma	2	0
Pericardial lipoma	1	0
<i>Cartilage sarcomas</i>		
Chondrosarcoma	1	0
<i>Central nervous system neoplasms malignant NEC</i>		
Brain cancer metastatic	1	0
<i>Cervix neoplasms malignant</i>		
Cervix carcinoma	2	0
<i>Colorectal neoplasms malignant</i>		
Colon cancer	2	0
Colorectal cancer	1	0
Rectal cancer	2	0
<i>Endocrine neoplasms malignant and unspecified NEC</i>		
Neuroendocrine tumour	1	0
Thyroid neoplasm	1	0
<i>Endometrial neoplasms malignant</i>		
Endometrial cancer	2	0
<i>Follicular lymphomas</i>		
Primary gastrointestinal follicular lymphoma	1	0
<i>Gastric neoplasms malignant</i>		
Gastric cancer	1	1
<i>Gastrointestinal neoplasms malignant NEC</i>		
Gastrointestinal carcinoma	3	0
<i>Hepatic neoplasms malignant</i>		
Hepatocellular carcinoma	1	0
<i>Hepatobiliary neoplasms malignancy unspecified</i>		
Hepatic neoplasm	1	0
<i>Hodgkin's disease NEC</i>		
Hodgkin's disease	4	0
<i>Islet cell neoplasms and APUDoma NEC</i>		

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Neoplasms</b> Neoplasms cont'd		
Pancreatic neuroendocrine tumour	1	0
<b><i>Kaposi's sarcomas</i></b>		
Kaposi's sarcoma	1	0
<b><i>Leukaemias NEC</i></b>		
Leukaemia	5	1
<b><i>Leukaemias acute NEC</i></b>		
Acute leukaemia	2	0
<b><i>Leukaemias chronic NEC</i></b>		
Chronic leukaemia	1	0
<b><i>Leukaemias chronic lymphocytic</i></b>		
Chronic lymphocytic leukaemia	3	0
<b><i>Leukaemias chronic myeloid</i></b>		
Chronic myeloid leukaemia	1	0
<b><i>Lip and oral cavity neoplasms malignant</i></b>		
Lip and/or oral cavity cancer recurrent	1	0
<b><i>Lymphomas unspecified NEC</i></b>		
Lymphoma	46	1
<b><i>Lymphoproliferative disorders NEC (excl leukaemias and lymphomas)</i></b>		
Histiocytic necrotising lymphadenitis	1	0
<b><i>Metastases to specified sites</i></b>		
Metastases to bone	1	0
Metastases to liver	1	0
Metastases to lymph nodes	5	0
<b><i>Metastases to unknown and unspecified sites</i></b>		
Metastasis	1	0
<b><i>Myelodysplastic syndromes</i></b>		
Myelodysplastic syndrome	3	0
<b><i>Myeloproliferative disorders (excl leukaemias)</i></b>		
Essential thrombocythaemia	2	0
<b><i>Neoplasms malignant site unspecified NEC</i></b>		
Adenocarcinoma metastatic	1	0
Metastatic neoplasm	2	0
Neoplasm malignant	11	1
Second primary malignancy	1	0
Squamous cell carcinoma	5	0
<b><i>Neoplasms unspecified malignancy and site unspecified NEC</i></b>		
Neoplasm	2	0
Neoplasm recurrence	1	0
<b><i>Nervous system neoplasms benign NEC</i></b>		
Cranial nerve neoplasm benign	1	0
Neurilemmoma benign	1	0
<b><i>Nervous system neoplasms unspecified malignancy NEC</i></b>		
Brain neoplasm	3	0
Meningioma	1	0
Spinal cord neoplasm	1	1
<b><i>Neuromas</i></b>		
Acoustic neuroma	3	0
Neuroma	1	0
<b><i>Non-Hodgkin's lymphomas NEC</i></b>		
Non-Hodgkin's lymphoma	3	0
<b><i>Ocular neoplasms benign</i></b>		
Eye naevus	3	0
<b><i>Ocular neoplasms malignancy unspecified</i></b>		

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Neoplasms</b> Neoplasms cont'd		
Eyelid tumour	1	0
<b><i>Oesophageal neoplasms malignant</i></b>		
Oesophageal cancer metastatic	4	0
<b><i>Oncologic complications and emergencies</i></b>		
Cancer pain	1	0
Tumour haemorrhage	1	0
<b><i>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</i></b>		
Tonsil cancer	4	0
<b><i>Ovarian neoplasms malignant (excl germ cell)</i></b>		
Ovarian cancer	1	0
<b><i>Pancreatic neoplasms malignant (excl islet cell and carcinoid)</i></b>		
Pancreatic carcinoma	4	0
<b><i>Plasma cell myelomas</i></b>		
POEMS syndrome	1	0
Plasma cell myeloma	2	0
<b><i>Plasma cell neoplasms NEC</i></b>		
Hypergammaglobulinaemia benign monoclonal	1	0
TEMPI syndrome	2	0
<b><i>Prostatic neoplasms malignant</i></b>		
Prostate cancer	4	0
<b><i>Renal neoplasms malignant</i></b>		
Clear cell renal cell carcinoma	1	0
Renal cancer	3	0
<b><i>Reproductive neoplasms female benign NEC</i></b>		
Benign hydatidiform mole	5	0
<b><i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i></b>		
Bronchial carcinoma	1	0
Lung cancer metastatic	1	1
Lung neoplasm malignant	15	1
<b><i>Salivary gland neoplasms unspecified malignancy</i></b>		
Salivary gland neoplasm	2	0
<b><i>Skin melanomas (excl ocular)</i></b>		
Malignant melanoma	3	0
Metastatic malignant melanoma	1	0
<b><i>Skin neoplasms benign</i></b>		
Acrochordon	6	0
Anogenital warts	7	0
Fibrous histiocytoma	1	0
Haemangioma of skin	7	0
Melanocytic naevus	10	0
Pyogenic granuloma	1	0
Seborrhoeic keratosis	1	0
Skin papilloma	21	0
<b><i>Skin neoplasms malignant and unspecified (excl melanoma)</i></b>		
Basal cell carcinoma	3	0
Bowen's disease	1	0
Neoplasm skin	3	0
Skin cancer	1	0
Squamous cell carcinoma of skin	1	0
<b><i>Soft tissue neoplasms benign NEC</i></b>		
Lipoma	7	0

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Reaction Name	Total	Fatal
<b>Neoplasms</b> Neoplasms cont'd		
Lymphangioma	1	0
<i>Soft tissue sarcomas histology unspecified</i>		
Sarcoma	1	0
<i>Thyroid neoplasms malignant</i>		
Hurthle cell carcinoma	1	0
Papillary thyroid cancer	2	0
Thyroid cancer	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	14	0
<b>Neoplasms SOC TOTAL</b>	<b>357</b>	<b>9</b>

## Case Series Drug Analysis Print

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Report Run Date: 17-Feb-2022

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i><b>Abnormal reflexes</b></i>		
Areflexia	8	0
Extensor plantar response	2	0
Hoffmann's sign	1	0
Hyperreflexia	4	0
Hyporeflexia	10	0
Reflexes abnormal	2	0
<i><b>Abnormal sleep-related events</b></i>		
Sleep paralysis	31	0
<i><b>Absence seizures</b></i>		
Petit mal epilepsy	29	0
<i><b>Acute polyneuropathies</b></i>		
Acute motor axonal neuropathy	1	0
Acute motor-sensory axonal neuropathy	1	0
Guillain-Barre syndrome	95	2
Miller Fisher syndrome	5	1
Subacute inflammatory demyelinating polyneuropathy	1	0
<i><b>Alzheimer's disease (incl subtypes)</b></i>		
Dementia Alzheimer's type	1	1
<i><b>Autonomic nervous system disorders</b></i>		
Anticholinergic syndrome	1	0
Autonomic nervous system imbalance	11	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>		
Basal ganglia haemorrhage	1	0
Basal ganglia infarction	1	0
Brain stem haemorrhage	2	2
Brain stem infarction	1	1
Brain stem stroke	2	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	9	1
Cerebral artery embolism	3	1
Cerebral artery occlusion	2	0
Cerebral artery thrombosis	4	0
Cerebral haemorrhage	60	14
Cerebral infarction	30	2
Cerebral ischaemia	1	0
Cerebral thrombosis	14	0
Cerebrovascular accident	481	19
Embolic stroke	8	0
Haemorrhage intracranial	13	3
Haemorrhagic cerebral infarction	1	0
Haemorrhagic stroke	12	5

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Internal capsule infarction	1	0
Intracranial haematoma	1	0
Ischaemic cerebral infarction	1	0
Ischaemic stroke	57	3
Lacunar infarction	4	0
Lacunar stroke	6	0
Lateral medullary syndrome	2	0
Pseudostroke	2	0
Ruptured cerebral aneurysm	1	0
Spinal stroke	1	0
Stroke in evolution	1	0
Subarachnoid haemorrhage	19	8
Thalamic infarction	1	0
Thrombotic stroke	6	1
Vertebrobasilar stroke	1	0
<b>Central nervous system inflammatory disorders NEC</b>		
Arachnoiditis	1	0
Gliosis	1	0
<b>Central nervous system vascular disorders NEC</b>		
Brain hypoxia	5	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	3	0
Cerebrovascular disorder	3	0
Post cardiac arrest syndrome	1	0
Reversible cerebral vasoconstriction syndrome	1	0
<b>Cerebrovascular venous and sinus thrombosis</b>		
Cerebral venous sinus thrombosis	54	5
Cerebral venous thrombosis	9	0
Superior sagittal sinus thrombosis	6	0
Transverse sinus thrombosis	2	0
<b>Cervical spinal cord and nerve root disorders</b>		
Cervical radiculopathy	2	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	16	0
Diabetic coma	1	0
Hypoglycaemic coma	1	0
<b>Coordination and balance disturbances</b>		
Ataxia	20	0
Balance disorder	490	0
Cerebellar ataxia	1	0
Cerebellar syndrome	1	0
Coordination abnormal	72	0
Dysdiadochokinesis	1	0



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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Dysstasia	72	0
Nystagmus	16	0
<b>Cortical dysfunction NEC</b>		
Alexia	2	0
Aphasia	101	0
Apraxia	1	0
Dysgraphia	2	0
Dyslexia	1	0
Dyspraxia	1	0
Neurologic neglect syndrome	1	0
Sensory processing disorder	3	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	18	0
Dementia with Lewy bodies	1	0
Senile dementia	1	0
<b>Demyelinating disorders NEC</b>		
Acute disseminated encephalomyelitis	7	0
Clinically isolated syndrome	1	0
Demyelination	9	0
Neuromyelitis optica spectrum disorder	2	0
<b>Disturbances in consciousness NEC</b>		
Altered state of consciousness	14	0
Consciousness fluctuating	3	0
Depressed level of consciousness	52	0
Infant sedation	1	0
Lethargy	2509	0
Loss of consciousness	791	1
Postictal state	5	0
Sedation	9	0
Somnolence	1188	0
Stupor	5	0
Syncope	2726	0
<b>Disturbances in sleep phase rhythm</b>		
Circadian rhythm sleep disorder	1	0
Irregular sleep phase	2	0
Irregular sleep wake rhythm disorder	2	0
Non-24-hour sleep-wake disorder	1	0
<b>Dyskinesias and movement disorders NEC</b>		
Akathisia	7	0
Ballismus	1	0
Bradykinesia	24	0
Clumsiness	23	0
Dyskinesia	79	0
Extrapyramidal disorder	3	0
Fine motor skill dysfunction	13	0
Foetal movement disorder	7	0
Hyperkinesia	4	0
Hypokinesia	105	0
Micrographia	1	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small>		
Motor dysfunction	4	0
Movement disorder	70	0
Psychomotor hyperactivity	29	0
Synkinesis	2	0
Tardive dyskinesia	2	0
<b>Dystonias</b>		
Dystonia	16	0
Writer's cramp	1	0
<b>Encephalitis NEC</b>		
Encephalitis autoimmune	1	0
Limbic encephalitis	1	0
Noninfective encephalitis	7	0
<b>Encephalopathies NEC</b>		
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	2	0
VIth nerve disorder	1	0
VIth nerve paralysis	11	0
<b>Facial cranial nerve disorders</b>		
Bell's palsy	623	0
Facial nerve disorder	9	0
Facial paralysis	472	0
Facial paresis	104	0
Facial spasm	54	0
<b>Generalised tonic-clonic seizures</b>		
Generalised tonic-clonic seizure	76	0
<b>Headaches NEC</b>		
Cervicogenic headache	3	0
Cluster headache	286	0
Cold-stimulus headache	35	0
Drug withdrawal headache	3	0
Exertional headache	9	0
External compression headache	2	0
Headache	29855	1
Medication overuse headache	2	0
New daily persistent headache	8	0
Occipital neuralgia	17	0
Ophthalmoplegic migraine	1	0
Primary cough headache	4	0
Primary headache associated with sexual activity	10	0
Sinus headache	394	0
Tension headache	625	0
Thunderclap headache	23	0
Vascular headache	21	0
<b>Hydrocephalic conditions</b>		
Hydrocephalus	5	0
<b>Hypoglossal nerve disorders</b>		

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Tongue paralysis	1	0
<b>Increased intracranial pressure disorders</b>		
Brain compression	2	0
Brain oedema	13	2
Idiopathic intracranial hypertension	12	0
Intracranial pressure increased	6	0
<b>Intellectual disabilities</b>		
Intellectual disability	4	0
<b>Lumbar spinal cord and nerve root disorders</b>		
Sciatica	132	0
<b>Memory loss (excl dementia)</b>		
Amnesia	220	0
Memory impairment	243	0
Transient global amnesia	10	0
<b>Mental impairment (excl dementia and memory loss)</b>		
Cognitive disorder	103	0
Cognitive linguistic deficit	1	0
Disturbance in attention	394	0
Mental impairment	58	0
<b>Migraine headaches</b>		
Basilar migraine	1	0
Hemiplegic migraine	42	0
Migraine	3468	0
Migraine with aura	229	0
Migraine without aura	22	0
Ophthalmic migraine	7	0
Retinal migraine	37	0
Typical aura without headache	9	0
Vestibular migraine	28	0
<b>Mixed cranial nerve disorders</b>		
Bulbar palsy	2	0
<b>Mononeuropathies</b>		
Carpal tunnel syndrome	33	0
Cubital tunnel syndrome	4	0
Meralgia paraesthetica	2	0
Mononeuritis	2	0
Mononeuropathy	4	0
Nerve compression	30	0
Peripheral nerve lesion	2	0
Peroneal nerve palsy	20	0
Piriformis syndrome	2	0
Pudendal canal syndrome	3	0
Sciatic nerve neuropathy	2	0
Ulnar nerve palsy	2	0
Ulnar neuritis	3	0
Ulnar tunnel syndrome	2	0
<b>Motor neurone diseases</b>		
Lower motor neurone lesion	2	0
Motor neurone disease	7	2
Progressive bulbar palsy	1	0
Upper motor neurone lesion	1	0
<b>Multiple sclerosis acute and progressive</b>		
Band sensation	1	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small>		
Multiple sclerosis	37	0
Multiple sclerosis relapse	26	0
Relapsing-remitting multiple sclerosis	1	0
Tumefactive multiple sclerosis	1	1
<b>Muscle tone abnormal</b>		
Drop attacks	2	0
Hypertonia	2	0
Hypotonia	36	0
Morvan syndrome	1	0
Muscle tone disorder	1	0
Serotonin syndrome	1	0
Stiff leg syndrome	1	0
<b>Myelitis (incl infective)</b>		
Myelitis transverse	35	0
<b>Narcolepsy and hypersomnia</b>		
Cataplexy	3	0
Hypersomnia	124	0
Narcolepsy	6	0
<b>Nervous system disorders NEC</b>		
Central nervous system lesion	2	0
Cerebral disorder	2	0
Nervous system disorder	22	0
Neurotoxicity	4	0
Psychomotor skills impaired	1	0
<b>Neurologic visual problems NEC</b>		
Hemianopia	1	0
Hemianopia homonymous	2	0
Quadrantanopia	2	0
Tunnel vision	23	0
<b>Neurological signs and symptoms NEC</b>		
Agitation neonatal	1	0
Cerebrospinal fluid leakage	1	0
Clonus	5	0
Decerebrate posture	1	0
Decorticate posture	1	0
Dizziness	11174	0
Dizziness exertional	51	0
Dizziness postural	844	0
Drooling	25	0
Fontanelle bulging	2	0
Head discomfort	396	0
Hyporesponsive to stimuli	2	0
Inability to crawl	3	0
Infant irritability	10	0
Meningism	2	0
Myoclonus	34	0
Neurological symptom	64	0
Patient elopement	1	0
Persistent postural-perceptual dizziness	17	0
Presyncope	706	0
Sensory overload	5	0
Slow response to stimuli	4	0
Tongue biting	8	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
Nervous system disorders cont'd		
Unresponsive to stimuli	59	0
<b>Neuromuscular disorders NEC</b>		
Muscle contractions involuntary	31	0
Muscle spasticity	19	0
Neuromuscular pain	3	0
<b>Neuromuscular junction dysfunction</b>		
Myasthenia gravis	10	0
Myasthenia gravis crisis	2	0
Myasthenic syndrome	1	0
<b>Olfactory nerve disorders</b>		
Anosmia	326	0
Hyposmia	18	0
Parosmia	319	0
<b>Optic nerve disorders NEC</b>		
Optic neuritis	38	0
<b>Paraesthesias and dysaesthesias</b>		
Burning feet syndrome	13	0
Burning sensation	647	0
Burning sensation mucosal	2	0
Dysaesthesia	8	0
Formication	46	0
Hand-arm vibration syndrome	3	0
Hemianaesthesia	4	0
Hemiparaesthesia	5	0
Hyperaesthesia	121	0
Hypoaesthesia	3447	0
Lhermitte's sign	1	0
Paraesthesia	4723	0
Reversed hot-cold sensation	4	0
Synaesthesia	1	0
<b>Paralysis and paresis (excl cranial nerve)</b>		
Diplegia	19	0
Hemiparesis	67	0
Hemiplegia	47	0
Locked-in syndrome	1	0
Monoparesis	91	0
Monoplegia	102	0
Paralysis	152	0
Paraparesis	3	0
Paraplegia	3	0
Paresis	10	0
Quadriparesis	1	0
Quadriplegia	1	0
<b>Parkinson's disease and parkinsonism</b>		
Freezing phenomenon	17	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	11	0
<b>Partial complex seizures</b>		
Dreamy state	6	0

## Case Series Drug Analysis Print

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

Report Run Date: 17-Feb-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small>		
Focal dyscognitive seizures	5	0
Temporal lobe epilepsy	2	0
<b>Partial simple seizures NEC</b>		
Autonomic seizure	1	0
<b>Peripheral neuropathies NEC</b>		
Axonal neuropathy	2	0
Brachial plexopathy	1	0
Neuralgic amyotrophy	5	0
Neuritis	9	0
Neuropathy peripheral	154	0
Peripheral sensorimotor neuropathy	1	0
Peripheral sensory neuropathy	12	0
Polyneuropathy	4	0
Small fibre neuropathy	4	0
Thoracic outlet syndrome	2	0
<b>Seizures and seizure disorders NEC</b>		
Atonic seizures	9	0
Change in seizure presentation	2	0
Clonic convulsion	5	0
Convulsions local	1	0
Convulsive threshold lowered	1	0
Epilepsy	168	0
Epileptic aura	2	0
Epileptic encephalopathy	2	0
Febrile convulsion	19	0
Idiopathic generalised epilepsy	1	0
Neonatal epileptic seizure	1	0
Partial seizures	29	0
Partial seizures with secondary generalisation	1	0
Post stroke seizure	1	0
Psychogenic seizure	11	0
Seizure	722	1
Seizure anoxic	3	0
Seizure cluster	7	0
Seizure like phenomena	3	0
Status epilepticus	39	0
Tonic clonic movements	5	0
Tonic convulsion	35	0
Tonic posturing	1	0
<b>Sensory abnormalities NEC</b>		
Ageusia	597	0
Allodynia	31	0
Aura	28	0
Central pain syndrome	1	0
Complex regional pain syndrome	6	0
Dysgeusia	1301	0
Electric shock sensation	50	0
Hypergeusia	1	0
Hypogeusia	9	0
Intercostal neuralgia	1	0
Loss of proprioception	3	0
Morton's neuralgia	4	0
Neuralgia	700	0

## Case Series Drug Analysis Print

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

Report Run Date: 17-Feb-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Persistent genital arousal disorder	2	0
Phantom limb syndrome	8	0
Post herpetic neuralgia	16	0
Restless arm syndrome	3	0
Restless legs syndrome	159	0
Sensory disturbance	125	0
Sensory loss	105	0
Taste disorder	307	0
Visual perseveration	3	0
<b>Sleep disturbances NEC</b>		
Microsleep	1	0
Sleep deficit	13	0
Sudden onset of sleep	1	0
<b>Speech and language abnormalities</b>		
Dysarthria	235	0
Incoherent	14	0
Language disorder	2	0
Repetitive speech	5	0
Slow speech	23	0
Speech disorder	80	0
Speech disorder developmental	1	0
<b>Spinal cord and nerve root disorders NEC</b>		
Acquired syringomyelia	1	0
Cauda equina syndrome	1	0
Myelopathy	1	0
Radiculitis brachial	17	0
Radiculopathy	8	0
<b>Structural brain disorders NEC</b>		
Brain injury	9	2
Cerebral ventricle dilatation	2	0
Hyperintensity in brain deep nuclei	1	0
Intracranial mass	1	0
<b>Transient cerebrovascular events</b>		
Transient ischaemic attack	193	3
<b>Tremor (excl congenital)</b>		
Essential tremor	5	0
Head titubation	13	0
Resting tremor	4	0
Tremor	2100	0
<b>Trigeminal disorders</b>		
Numb chin syndrome	2	0
Trigeminal nerve disorder	3	0
Trigeminal neuralgia	83	0
Trigeminal neuritis	3	0
<b>Vagus nerve disorders</b>		
Vocal cord paralysis	4	0
<b>Vertigos NEC</b>		
Cervicogenic vertigo	1	0
Vertigo CNS origin	3	0
<b>Nervous system disorders SOC TOTAL</b>	<b>79123</b>	<b>85</b>

## Case Series Drug Analysis Print

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

Report Run Date: 17-Feb-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i><b>Abortion related conditions and complications</b></i>		
Anembryonic gestation	3	0
<i><b>Abortions not specified as induced or spontaneous</b></i>		
Abortion	1	0
Abortion missed	7	0
<i><b>Abortions spontaneous</b></i>		
Abortion spontaneous	474	0
Abortion threatened	2	0
<i><b>Amniotic fluid and cavity disorders of pregnancy NEC</b></i>		
Amniorrhoea	2	0
Oligohydramnios	1	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 conditions due to maternal conditions</b></i>		
Maternal condition affecting foetus	1	0
<i><b>Foetal growth complications</b></i>		
Foetal growth restriction	7	0
<i><b>Gestational age and weight conditions</b></i>		
Low birth weight baby	1	0
Premature baby	7	1
<i><b>Haemorrhagic complications of pregnancy</b></i>		
Haemorrhage in pregnancy	3	0
Premature separation of placenta	3	0
Retroplacental haematoma	1	0
Subchorionic haematoma	3	0
Subchorionic haemorrhage	1	0
<i><b>Hypertension associated disorders of pregnancy</b></i>		
Pre-eclampsia	2	0
<i><b>Labour onset and length abnormalities</b></i>		
Induced labour	1	0
Premature delivery	1	0
Premature labour	8	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	4	0
Complication of pregnancy	1	0
Decidual cast	5	0
Ectopic pregnancy	14	0
Hyperemesis gravidarum	1	0
Morning sickness	16	0
Preterm premature rupture of membranes	3	0
Ruptured ectopic pregnancy	1	0
Somatic symptom disorder of pregnancy	3	0
<i><b>Neonatal hepatobiliary disorders</b></i>		
Jaundice neonatal	1	0



## Case Series Drug Analysis Print

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Report Run Date: 17-Feb-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Pregnancy conditions</b> <small>Pregnancy conditions cont'd</small>		
<b><i>Normal newborn status</i></b>		
Normal newborn	1	0
<b><i>Normal pregnancy, labour and delivery</i></b>		
Labour pain	1	0
Live birth	7	0
Pregnancy	35	0
Term birth	1	0
Uterine contractions during pregnancy	6	0
<b><i>Placental abnormalities (excl neoplasms)</i></b>		
Foetal vascular malperfusion	2	0
Placental disorder	1	0
Placental insufficiency	1	0
Small size placenta	1	0
<b><i>Postpartum complications NEC</i></b>		
Postpartum haemorrhage	5	0
<b><i>Pregnancy complicated by maternal disorders</i></b>		
Gestational diabetes	2	0
Peripartum cardiomyopathy	1	0
<b><i>Stillbirth and foetal death</i></b>		
Foetal death	3	3
Stillbirth	11	10
<b><i>Umbilical cord complications</i></b>		
Umbilical cord abnormality	1	0
Umbilical cord thrombosis	1	0
<b><i>Unintended pregnancies</i></b>		
Pregnancy after post coital contraception	2	0
Pregnancy on contraceptive	3	0
Pregnancy on oral contraceptive	2	0
Pregnancy with contraceptive device	2	0
Pregnancy with implant contraceptive	1	0
Unintended pregnancy	4	0
Unwanted pregnancy	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>705</b>	<b>14</b>

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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	21	0
Thrombosis in device	14	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>Manufacturing materials issues</i></b>		
Manufacturing materials contamination	1	0
<b><i>Product contamination and sterility issues</i></b>		
Product contamination	17	0
Product contamination physical	11	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	12	0
Product after taste	3	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	2	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>128</b>	<b>0</b>

## Case Series Drug Analysis Print

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

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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	7	0
Staring	8	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	15	0
Constricted affect	6	0
Flat affect	13	0
Inappropriate affect	23	0
<b><i>Amnesic symptoms</i></b>		
Paramnesia	7	0
<b><i>Anxiety disorders NEC</i></b>		
Anxiety disorder	2	0
Generalised anxiety disorder	3	0
Neurosis	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	92	0
Anxiety	1064	0
Immunisation anxiety related reaction	4	0
Nervousness	208	0
Stress	133	0
Tension	44	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	17	0
Attention-seeking behaviour	1	0
Aversion	1	0
Disinhibition	3	0
Indifference	7	0
Paranoia	31	0
Personality change	5	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	5	0
<b><i>Cognitive and attention disorders and disturbances NEC</i></b>		
Daydreaming	9	0
Distractibility	4	0
Mental fatigue	247	0
<b><i>Communications disorders</i></b>		
Communication disorder	5	0
Mutism	4	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	1045	0
Disorientation	326	0
<b><i>Decreased physical activity levels</i></b>		

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <sup>Psychiatric disorders cont'd</sup>		
Catatonia	1	0
<b>Deliria</b>		
Delirium	150	0
<b>Delusional symptoms</b>		
Delusion	18	0
<b>Depressive disorders</b>		
Agitated depression	6	0
Depression	410	0
Depression suicidal	19	0
Major depression	15	0
Mixed anxiety and depressive disorder	4	0
<b>Dissociative states</b>		
Depersonalisation/derealisation disorder	12	0
Dissociation	37	0
Dissociative amnesia	4	0
Dissociative disorder	2	0
<b>Disturbances in initiating and maintaining sleep</b>		
Initial insomnia	30	0
Insomnia	1929	0
Middle insomnia	34	0
Terminal insomnia	35	0
<b>Dyssomnias</b>		
Breathing-related sleep disorder	1	0
Dyssomnia	1	0
Poor quality sleep	268	0
<b>Eating disorders NEC</b>		
Bulimia nervosa	1	0
Eating disorder	13	0
Selective eating disorder	1	0
<b>Emotional and mood disturbances NEC</b>		
Anger	45	0
Dysphoria	2	0
Emotional disorder	71	0
Emotional distress	63	0
Emotional poverty	2	0
Euphoric mood	50	0
Frustration tolerance decreased	2	0
Irritability	235	0
Mood altered	63	0
Morose	1	0
<b>Factitious disorders</b>		
Factitious disorder	4	0
<b>Fear symptoms and phobic disorders (incl social phobia)</b>		
Agoraphobia	2	0
Claustrophobia	1	0
Fear	33	0
Fear of death	2	0
Fear of eating	1	0
Fear of falling	3	0
Fear of injection	6	0
Osmophobia	1	0
Performance fear	1	0
Phobia	3	0

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <sup>Psychiatric disorders cont'd</sup>		
Phonophobia	3	0
Social anxiety disorder	2	0
Social fear	1	0
<b>Fluctuating mood symptoms</b>		
Mood swings	168	0
<b>Hallucinations (excl sleep-related)</b>		
Hallucination	251	0
Hallucination, auditory	22	0
Hallucination, olfactory	15	0
Hallucination, tactile	1	0
Hallucination, visual	31	0
Hallucinations, mixed	4	0
<b>Increased physical activity levels</b>		
Restlessness	176	0
<b>Infancy, childhood and adolescence psychiatric disorders NEC</b>		
Social (pragmatic) communication disorder	1	0
<b>Learning disorders</b>		
Learning disability	1	0
Learning disorder	1	0
<b>Mental disorders NEC</b>		
Mental disorder	21	0
Mental status changes	1	0
Psychological factor affecting medical condition	1	0
<b>Mood alterations with depressive symptoms</b>		
Anhedonia	3	0
Decreased interest	11	0
Depressed mood	453	0
Depressive symptom	2	0
Feeling guilty	1	0
Feeling of despair	5	0
Feelings of worthlessness	2	0
Negative thoughts	3	0
Psychomotor retardation	2	0
Sense of a foreshortened future	3	0
Tearfulness	48	0
<b>Mood alterations with manic symptoms</b>		
Hypomania	2	0
Mania	11	0
<b>Mood disorders NEC</b>		
Affective disorder	4	0
Apathy	38	0
Boredom	1	0
Laziness	3	0
Listless	26	0
Mood disorder due to a general medical condition	1	0
<b>Narcolepsy and associated conditions</b>		
Hypnagogic hallucination	4	0
Hypnopompic hallucination	2	0
Sleep attacks	3	0
<b>Obsessive-compulsive disorders and symptoms</b>		
Obsessive-compulsive symptom	1	0
<b>Orgasmic disorders and disturbances</b>		
Anorgasmia	5	0

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <sup>Psychiatric disorders cont'd</sup>		
Female orgasmic disorder	2	0
Orgasm abnormal	4	0
Orgasmic sensation decreased	1	0
Premature ejaculation	1	0
<b>Panic attacks and disorders</b>		
Limited symptom panic attack	1	0
Panic attack	257	0
Panic disorder	9	0
Panic reaction	31	0
<b>Paraphilias and paraphilic disorders</b>		
Transvestism	1	0
<b>Parasomnias</b>		
Abnormal dreams	212	0
Abnormal sleep-related event	1	0
Confusional arousal	1	0
Exploding head syndrome	2	0
Nightmare	234	0
Parasomnia	4	0
Sleep inertia	1	0
Sleep talking	6	0
Sleep terror	29	0
Somnambulism	10	0
<b>Perception disturbances NEC</b>		
Autoscopy	20	0
Deja vu	3	0
Derealisation	13	0
Flashback	4	0
Illusion	6	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	31	0
<b>Psychiatric symptoms NEC</b>		
Helplessness	1	0
Hypervigilance	9	0
Psychiatric symptom	13	0
Psychological trauma	4	0
Trance	1	0
<b>Psychotic disorder NEC</b>		
Acute psychosis	1	0
Psychotic behaviour	1	0
Psychotic disorder	32	0
<b>Schizophrenia NEC</b>		
Schizophrenia	2	0
<b>Sexual and gender identity disorders NEC</b>		
Gender dysphoria	1	0
<b>Sexual arousal disorders</b>		
Disturbance in sexual arousal	4	0

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Sexual inhibition	1	0
<b>Sexual desire disorders</b>		
Hypersexuality	1	0
Libido decreased	20	0
Libido disorder	2	0
Libido increased	8	0
Loss of libido	22	0
<b>Sexual dysfunction NEC</b>		
Genito-pelvic pain/penetration disorder	2	0
<b>Sleep disorders NEC</b>		
Sleep disorder	281	0
Sleep disorder due to general medical condition, insomnia type	5	0
<b>Somatic symptom disorders</b>		
Conversion disorder	27	0
Habit cough	22	0
Somatic symptom disorder	2	0
Vomiting psychogenic	1	0
<b>Speech and language usage disturbances</b>		
Disorganised speech	10	0
Logorrhoea	2	0
<b>Speech articulation and rhythm disturbances</b>		
Dysphemia	27	0
Lack of spontaneous speech	1	0
Pressure of speech	1	0
<b>Stereotypies and automatisms</b>		
Automatism	1	0
Bruxism	15	0
Head banging	12	0
Stereotypy	1	0
<b>Stress disorders</b>		
Burnout syndrome	2	0
Post-traumatic stress disorder	5	0
<b>Substance related and addictive disorders</b>		
Alcohol problem	1	0
Alcoholic hangover	1	0
Alcoholism	5	0
Nicotine dependence	2	0
<b>Suicidal and self-injurious behaviour</b>		
Completed suicide	2	2
Intentional self-injury	6	0
Self-injurious ideation	2	0
Suicidal ideation	49	0
Suicide attempt	8	0
Suicide threat	2	0
<b>Thinking disturbances</b>		
Bradyphrenia	44	0
Flight of ideas	1	0
Intrusive thoughts	8	0
Morbid thoughts	1	0
Tachyphrenia	8	0
Thinking abnormal	21	0
Thought blocking	3	0
<b>Tic disorders</b>		

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Tic	17	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>9921</b>	<b>2</b>



## Case Series Drug Analysis Print

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

Report Run Date: 17-Feb-2022

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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i><b>Bladder and urethral symptoms</b></i>		
Bladder discomfort	3	0
Bladder irritation	13	0
Bladder pain	35	0
Bladder spasm	2	0
Dysuria	57	0
Incontinence	40	0
Lower urinary tract symptoms	3	0
Micturition disorder	2	0
Micturition urgency	52	0
Mixed incontinence	1	0
Pollakiuria	161	0
Stress urinary incontinence	2	0
Urethral pain	7	0
Urge incontinence	3	0
Urinary hesitation	4	0
Urinary incontinence	70	0
Urinary retention	55	0
Urine flow decreased	19	0
<i><b>Bladder disorders NEC</b></i>		
Bladder disorder	11	0
Bladder fibrosis	1	0
Bladder prolapse	1	0
Urinary bladder haemorrhage	4	0
<i><b>Bladder infections and inflammations</b></i>		
Cystitis haemorrhagic	1	0
Cystitis interstitial	6	0
Cystitis noninfective	1	0
<i><b>Bladder neoplasms</b></i>		
Bladder cyst	1	0
<i><b>Genital and urinary tract disorders NEC</b></i>		
Genitourinary symptom	3	0
Urinary tract disorder	4	0
<i><b>Glomerulonephritis and nephrotic syndrome</b></i>		
Glomerulonephritis minimal lesion	6	0
Glomerulonephritis rapidly progressive	2	0
IgA nephropathy	4	0
Nephrotic syndrome	19	0
<i><b>Myoneurogenic bladder disorders</b></i>		
Bladder dysfunction	6	0
Hypertonic bladder	5	0
Hypotonic urinary bladder	1	0
Loss of bladder sensation	3	0
Neurogenic bladder	2	0
<i><b>Nephritis NEC</b></i>		
Lupus nephritis	2	0
Nephritis	3	0
Tubulointerstitial nephritis	2	0
<i><b>Nephropathies and tubular disorders NEC</b></i>		
Nephropathy	1	0
<i><b>Renal disorders NEC</b></i>		
Kidney fibrosis	1	0
Renal disorder	7	1

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
Renal & urinary disorders cont'd		
Renal haemorrhage	1	0
Renal mass	1	0
<b>Renal failure and impairment</b>		
Acute kidney injury	51	4
Anuria	3	0
Chronic kidney disease	4	0
Oliguria	1	0
Renal failure	24	1
Renal impairment	29	0
Renal injury	2	0
<b>Renal failure complications</b>		
Azotaemia	1	0
<b>Renal lithiasis</b>		
Nephrolithiasis	12	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 enlargement	1	0
Kidney small	2	0
<b>Renal vascular and ischaemic conditions</b>		
Renal aneurysm	1	0
Renal infarct	4	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	67	0
Haematuria	51	0
Ketonuria	1	0
Myoglobinuria	1	0
Proteinuria	13	0
Urine abnormality	12	0
Urine odour abnormal	10	0
<b>Urinary tract lithiasis (excl renal)</b>		
Calculus bladder	1	0
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	30	1
Nocturia	3	0
Polyuria	9	0
Renal colic	4	0
Renal pain	358	0
Urinary tract discomfort	2	0
Urinary tract pain	6	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>1343</b>	<b>8</b>

## Case Series Drug Analysis Print

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

Report Run Date: 17-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

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	16	0
<i><b>Breast disorders NEC</b></i>		
Breast atrophy	1	0
Breast disorder	3	0
Breast enlargement	31	0
Breast mass	144	0
Fibrocystic breast disease	1	0
Gynaecomastia	7	0
Mastoptosis	1	0
Nipple disorder	1	0
<i><b>Breast infections and inflammations</b></i>		
Breast inflammation	6	0
Nipple inflammation	2	0
<i><b>Breast signs and symptoms</b></i>		
Breast discharge	5	0
Breast discomfort	15	0
Breast engorgement	11	0
Breast haematoma	1	0
Breast oedema	9	0
Breast pain	856	0
Breast swelling	191	0
Breast tenderness	102	0
Nipple pain	47	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	5	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	3	0
Ejaculation failure	3	0
Erectile dysfunction	74	0
Erection increased	4	0
Organic erectile dysfunction	14	0
Painful ejaculation	1	0
Spontaneous ejaculation	2	0
Spontaneous penile erection	2	0
<i><b>Fallopian tube and ovary infections and inflammations</b></i>		
Noninfective oophoritis	6	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	11	0
Lactation puerperal increased	6	0
Suppressed lactation	48	0

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Reproductive &amp; breast disorders cont'd</i>		
<b><i>Menopausal effects NEC</i></b>		
Artificial menopause	1	0
Menopausal disorder	1	0
Menopausal symptoms	46	0
Menopause delayed	1	0
Premature menopause	24	0
<b><i>Menopausal effects on the genitourinary tract</i></b>		
Atrophic vulvovaginitis	2	0
Postmenopausal haemorrhage	107	0
<b><i>Menstruation and uterine bleeding NEC</i></b>		
Abnormal uterine bleeding	6	0
Abnormal withdrawal bleeding	3	0
Bleeding anovulatory	1	0
Dysmenorrhoea	3274	0
Intermenstrual bleeding	1288	0
Menstrual discomfort	35	0
Menstrual disorder	2242	0
Menstruation irregular	3961	0
Premenstrual dysphoric disorder	14	0
Premenstrual headache	13	0
Premenstrual pain	146	0
Premenstrual syndrome	134	0
Retrograde menstruation	1	0
Withdrawal bleed	16	0
<b><i>Menstruation with decreased bleeding</i></b>		
Amenorrhoea	700	0
Hypomenorrhoea	747	0
Menstruation delayed	5618	0
Oligomenorrhoea	222	0
<b><i>Menstruation with increased bleeding</i></b>		
Heavy menstrual bleeding	6224	0
Menometrorrhagia	21	0
Polymenorrhoea	1018	0
<b><i>Ovarian and fallopian tube cysts and neoplasms</i></b>		
Haemorrhagic ovarian cyst	3	0
Ovarian cyst	29	0
Ovarian cyst ruptured	1	0
Polycystic ovaries	50	0
<b><i>Ovarian and fallopian tube disorders NEC</i></b>		
Adnexal torsion	1	0
Hydrosalpinx	2	0
Ovarian enlargement	1	0
Ovarian failure	1	0
Ovarian haemorrhage	8	0
Ovarian hyperstimulation syndrome	1	0
Ovarian mass	2	0
Ovarian necrosis	1	0
Ovulation disorder	4	0
Ovulation pain	82	0
Premature ovulation	4	0
Superovulation	1	0
<b><i>Pelvic prolapse conditions</i></b>		
Vaginal prolapse	1	0

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Reproductive &amp; breast disorders cont'd</i>		
<b><i>Pelvis and broad ligament disorders NEC</i></b>		
Adnexa uteri mass	1	0
Adnexa uteri pain	70	0
Pelvic congestion	1	0
Pelvic floor muscle weakness	1	0
Pelvic haemorrhage	22	0
<b><i>Penile and scrotal infections and inflammations</i></b>		
Balanoposthitis	4	0
<b><i>Penile disorders NEC (excl erection and ejaculation)</i></b>		
Foreskin oedema	1	0
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 rash	1	0
Penile size reduced	1	0
Penile swelling	6	0
Penis disorder	12	0
<b><i>Prostate and seminal vesicles infections and inflammations</i></b>		
Prostatitis	5	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	25	0
Genital hypoaesthesia	1	0
Genital lesion	2	0
Genital paraesthesia	1	0
Genital ulceration	8	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	7	0
Genital rash	6	0
Genital swelling	5	0
Pelvic discomfort	6	0
Pelvic pain	129	0
Perineal pain	2	0
Perineal rash	1	0
Pruritus genital	6	0
<b><i>Scrotal disorders NEC</i></b>		
Acquired hydrocele	1	0
Scrotal angiokeratoma	1	0
Scrotal discomfort	1	0

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Reproductive &amp; breast disorders cont'd</i>		
Scrotal erythema	2	0
Scrotal exfoliation	2	0
Scrotal pain	22	0
Scrotal swelling	5	0
Scrotum erosion	1	0
Varicocele	2	0
<b><i>Sexual function and fertility disorders NEC</i></b>		
Dyspareunia	7	0
Infertility	16	0
Infertility female	5	0
Sexual dysfunction	9	0
<b><i>Spermatogenesis and semen disorders</i></b>		
Aspermia	1	0
Haematospermia	8	0
Semen discolouration	1	0
<b><i>Testicular and epididymal disorders NEC</i></b>		
Testicular atrophy	1	0
Testicular disorder	4	0
Testicular oedema	1	0
Testicular pain	70	0
Testicular swelling	13	0
Testicular torsion	1	0
Testis discomfort	3	0
<b><i>Testicular and epididymal neoplasms</i></b>		
Testicular cyst	1	0
<b><i>Uterine disorders NEC</i></b>		
Adenomyosis	11	0
Endometrial thickening	4	0
Endometriosis	96	0
Uterine haemorrhage	45	0
Uterine pain	19	0
<b><i>Uterine infections and inflammations (excl cervix)</i></b>		
Uterine inflammation	1	0
<b><i>Uterine neoplasms</i></b>		
Uterine polyp	5	0
<b><i>Uterine tone disorders</i></b>		
Uterine spasm	39	0
<b><i>Vaginal and vulval infections and inflammations</i></b>		
Vulvovaginal inflammation	1	0
<b><i>Vulvovaginal cysts and neoplasms</i></b>		
Bartholin's cyst	2	0
Vaginal cyst	7	0
Vaginal polyp	1	0
Vulva cyst	1	0
<b><i>Vulvovaginal disorders NEC</i></b>		
Vaginal haemorrhage	1778	0
Vaginal mucosal blistering	1	0
Vaginal ulceration	4	0
Vulval disorder	2	0
Vulval haemorrhage	34	0
Vulval ulceration	7	0
Vulvovaginal ulceration	6	0
<b><i>Vulvovaginal signs and symptoms</i></b>		

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<small>Reproductive &amp; breast disorders cont'd</small>		
Clitoral engorgement	1	0
Coital bleeding	7	0
Labia enlarged	2	0
Vaginal discharge	88	0
Vaginal lesion	1	0
Vaginal odour	4	0
Vulval oedema	2	0
Vulvovaginal burning sensation	9	0
Vulvovaginal discomfort	2	0
Vulvovaginal dryness	5	0
Vulvovaginal erythema	2	0
Vulvovaginal pain	30	0
Vulvovaginal pruritus	10	0
Vulvovaginal rash	2	0
Vulvovaginal swelling	5	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>30469</b>	<b>1</b>

## Case Series Drug Analysis Print

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

Report Run Date: 17-Feb-2022

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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	6643	5
Dyspnoea at rest	11	0
Dyspnoea exertional	44	1
Grunting	1	0
Hyperventilation	60	0
Hypopnoea	129	0
Hypoventilation	1	0
Irregular breathing	26	0
Mouth breathing	7	0
Nocturnal dyspnoea	2	0
Orthopnoea	3	0
Respiration abnormal	70	0
Respiratory arrest	20	0
Respiratory depression	1	0
Respiratory distress	20	0
Sleep apnoea syndrome	15	0
Tachypnoea	31	0
<i><b>Bronchial conditions NEC</b></i>		
Bronchial secretion retention	4	0
Bronchiectasis	15	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	419	0
Asthma late onset	3	0
Bronchospasm	19	0
Chronic obstructive pulmonary disease	26	1
Cough variant asthma	7	0
Obstructive airways disorder	13	0
Reversible airways obstruction	1	0
Wheezing	469	0
<i><b>Conditions associated with abnormal gas exchange</b></i>		
Asphyxia	2	0
Cyanosis central	1	0
Hyperoxia	1	0
Hypoxia	32	2
Respiratory acidosis	2	0
<i><b>Coughing and associated symptoms</b></i>		
Allergic cough	9	0
Cough	2934	1
Cough decreased	2	0
Haemoptysis	72	0
Productive cough	196	0
Sputum discoloured	11	0
Sputum increased	4	0
<i><b>Diaphragmatic disorders</b></i>		
Acquired diaphragmatic eventration	1	0
Diaphragm muscle weakness	1	0
Diaphragmatic disorder	1	0
<i><b>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</b></i>		
Laryngeal disorder	1	0



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Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
Reflux laryngitis	3	0
Vocal cord disorder	1	0
Vocal cord dysfunction	3	0
<b><i>Laryngeal spasm, oedema and obstruction</i></b>		
Epiglottic oedema	1	0
Laryngeal obstruction	1	0
Laryngeal oedema	4	0
Laryngospasm	3	0
Stridor	27	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	35	2
Pulmonary sarcoidosis	2	0
<b><i>Lower respiratory tract signs and symptoms</i></b>		
Hiccups	36	0
Increased bronchial secretion	3	0
Increased viscosity of bronchial secretion	1	0
Lung hyperinflation	2	0
Lung opacity	3	0
Pleuritic pain	26	0
Pulmonary haemorrhage	1	0
Pulmonary pain	120	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	332	0
Nasal inflammation	4	0
Rhinitis allergic	26	0
<b><i>Nasal disorders NEC</i></b>		
Epistaxis	1064	0
Intranasal hypoaesthesia	2	0
Intranasal paraesthesia	1	0
Nasal crusting	2	0
Nasal disorder	4	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	2	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	3	0

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
Paranasal sinus inflammation	4	0
Sinonasal obstruction	14	0
Sinus congestion	71	0
Sinus disorder	7	0
<b><i>Parenchymal lung disorders NEC</i></b>		
Atelectasis	4	0
Combined pulmonary fibrosis and emphysema	1	0
Emphysema	3	0
Interstitial lung disease	11	0
Lung consolidation	5	0
Lung infiltration	2	1
Organising pneumonia	2	0
Pulmonary alveolar haemorrhage	1	0
Pulmonary cavitation	1	0
Pulmonary fibrosis	9	0
Pulmonary toxicity	1	0
<b><i>Pharyngeal disorders (excl infections and neoplasms)</i></b>		
Hyperactive pharyngeal reflex	1	0
Pharyngeal enanthema	1	0
Pharyngeal erythema	9	0
Pharyngeal haemorrhage	2	0
Pharyngeal hypoaesthesia	40	0
Pharyngeal inflammation	4	0
Pharyngeal lesion	1	0
Pharyngeal mass	1	0
Pharyngeal oedema	14	0
Pharyngeal paraesthesia	56	0
Pharyngeal swelling	297	0
Pharyngeal ulceration	16	0
Tonsillar erythema	13	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	97	0
Tonsillar inflammation	3	0
Tonsillar ulcer	1	0
Tonsillolith	1	0
<b><i>Pleural infections and inflammations</i></b>		
Pleurisy	37	0
<b><i>Pneumothorax and pleural effusions NEC</i></b>		
Pleural effusion	40	0
Pneumothorax	12	0
Pneumothorax spontaneous	5	0
<b><i>Pulmonary hypertensions</i></b>		
Pulmonary hypertension	3	0
<b><i>Pulmonary oedemas</i></b>		
Acute respiratory distress syndrome	2	1
Pulmonary congestion	19	0
Pulmonary oedema	23	2
<b><i>Pulmonary thrombotic and embolic conditions</i></b>		
Pulmonary artery thrombosis	2	0
Pulmonary embolism	532	37
Pulmonary infarction	6	0
Pulmonary thrombosis	11	1
<b><i>Respiratory failures (excl neonatal)</i></b>		

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
Acute respiratory failure	3	1
Respiratory failure	15	2
<b><i>Respiratory signs and symptoms NEC</i></b>		
Allergic respiratory symptom	6	0
Diaphragmalgia	9	0
Nasal flaring	1	0
Painful respiration	17	1
Pleural rub	1	0
Respiratory symptom	21	0
Suffocation feeling	2	0
Use of accessory respiratory muscles	2	0
<b><i>Respiratory tract disorders NEC</i></b>		
Allergic respiratory disease	1	0
Aspiration	4	0
Lung disorder	10	0
Pulmonary mass	5	0
Respiratory disorder	16	1
Respiratory tract congestion	5	0
Respiratory tract haemorrhage	2	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	139	0
Catarrh	32	0
Choking	20	0
Choking sensation	6	0
Dry throat	185	0
Dysphonia	183	0
Increased upper airway secretion	6	0
Increased viscosity of upper respiratory secretion	35	0
Laryngeal pain	1	0
Nasal discharge discolouration	4	0
Nasal discomfort	58	0
Nasal obstruction	3	0
Oropharyngeal blistering	11	0
Oropharyngeal discolouration	1	0
Oropharyngeal discomfort	71	0
Oropharyngeal pain	3218	0
Oropharyngeal plaque	2	0
Paranasal sinus discomfort	53	0
Rhinalgia	14	0
Rhinorrhoea	1056	0
Sinus pain	248	0
Sneezing	446	0
Snoring	8	0

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
Throat clearing	8	0
Throat irritation	264	0
Throat lesion	1	0
Throat tightness	283	0
Upper airway obstruction	3	0
Upper respiratory tract congestion	2	0
Upper respiratory tract irritation	1	0
Upper-airway cough syndrome	15	0
Yawning	30	0
<b><i>Vascular pulmonary disorders NEC</i></b>		
Acute chest syndrome	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>21064</b>	<b>59</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Acnes</i></b>		
Acne	215	0
Acne cystic	28	0
Dermatitis acneiform	13	0
Oil acne	1	0
<b><i>Alopecias</i></b>		
Alopecia	421	0
Alopecia areata	68	0
Alopecia totalis	3	0
Alopecia universalis	2	0
Androgenetic alopecia	2	0
Diffuse alopecia	4	0
Hypotrichosis	3	0
Lichen planopilaris	1	0
Madarosis	9	0
<b><i>Angioedemas</i></b>		
Angioedema	277	0
Circumoral oedema	1	0
Circumoral swelling	1	0
Idiopathic angioedema	1	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Anhidrosis	2	0
Bromhidrosis	1	0
Cold sweat	874	0
Hidradenitis	5	0
Hyperhidrosis	2667	0
Hypohidrosis	2	0
Milia	2	0
Miliaria	118	0
Night sweats	932	0
Sweat discolouration	1	0
<b><i>Bullous conditions</i></b>		
Autoimmune blistering disease	1	0
Blister	534	0
Blister rupture	1	0
Blood blister	35	0
Dermatitis bullous	16	0
Erythema multiforme	44	0
Fracture blisters	1	0
Herpes gestationis	1	0
Pemphigoid	30	0
Pemphigus	9	0
Stevens-Johnson syndrome	6	0
Toxic epidermal necrolysis	2	1
<b><i>Connective tissue disorders</i></b>		
Cutaneous lupus erythematosus	3	0
Dermatomyositis	10	0
Subacute cutaneous lupus erythematosus	3	0
<b><i>Dermal and epidermal conditions NEC</i></b>		
Acute febrile neutrophilic dermatosis	1	0
Dermatosis	1	0
Dry skin	289	0
Koebner phenomenon	1	0

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Macule	5	0
Neutrophilic dermatosis	1	0
Pain of skin	335	0
Papule	117	0
Pathergy reaction	1	0
Scab	26	0
Scar discomfort	1	0
Scar pain	20	0
Sensitive skin	228	0
Shagreen skin	1	0
Skin burning sensation	262	0
Skin degenerative disorder	1	0
Skin discolouration	159	0
Skin discomfort	4	0
Skin disorder	35	0
Skin fissures	9	0
Skin indentation	3	0
Skin induration	5	0
Skin lesion	50	0
Skin lesion inflammation	1	0
Skin necrosis	2	0
Skin odour abnormal	25	0
Skin plaque	4	0
Skin reaction	169	0
Skin sensitisation	45	0
Skin swelling	115	0
Skin texture abnormal	2	0
Skin tightness	29	0
Skin warm	366	0
Skin weeping	13	0
Sticky skin	3	0
Target skin lesion	3	0
Transient acantholytic dermatosis	1	0
Yellow skin	29	0
<b><i>Dermatitis and eczema</i></b>		
Dermatitis	161	0
Dermatitis allergic	299	0
Dermatitis atopic	59	0
Dermatitis contact	26	0
Dermatitis diaper	4	0
Dyshidrotic eczema	32	0
Eczema	405	0
Eczema asteatotic	14	0
Eczema infantile	1	0
Eczema nummular	7	0
Eczema weeping	6	0
Hand dermatitis	2	0
Intertrigo	1	0
Neurodermatitis	4	0
Perioral dermatitis	3	0
Seborrhoeic dermatitis	7	0
Skin irritation	151	0
Stasis dermatitis	2	0

## Case Series Drug Analysis Print

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

Report Run Date: 17-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
<b><i>Dermatitis ascribed to specific agent</i></b>		
Drug eruption	35	0
Drug reaction with eosinophilia and systemic symptoms	1	0
Fixed eruption	2	0
Palmar-plantar erythrodysesthesia syndrome	3	0
Toxic skin eruption	2	0
<b><i>Erythemas</i></b>		
Erythema	2472	0
Palmar erythema	4	0
Pernio-like erythema	1	0
Red man syndrome	2	0
<b><i>Exfoliative conditions</i></b>		
Dermatitis exfoliative	2	0
Dermatitis exfoliative generalised	5	0
Exfoliative rash	26	0
Keratolysis exfoliativa acquired	2	0
Skin exfoliation	141	0
<b><i>Granulomatous and deep cutaneous inflammatory conditions</i></b>		
Cutaneous sarcoidosis	1	0
Granuloma annulare	7	0
Necrobiosis lipoidica diabetorum	1	0
<b><i>Hyperkeratoses</i></b>		
Hyperkeratosis	2	0
Keratosis pilaris	3	0
Lichenoid keratosis	4	0
<b><i>Hyperpigmentation disorders</i></b>		
Argyria	1	0
Chloasma	2	0
Ephelides	1	0
Skin hyperpigmentation	7	0
Solar lentigo	4	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	23	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>		
Ingrowing nail	2	0
Nail discolouration	12	0
Nail disorder	7	0
Nail growth abnormal	1	0
Nail pigmentation	2	0
Nail ridging	3	0
Onychalgia	9	0
Onychoclasia	6	0
Onychomadesis	2	0
Splinter haemorrhages	3	0
<b><i>Panniculitides</i></b>		

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Erythema nodosum	34	0
Panniculitis	2	0
<b><i>Papulosquamous conditions</i></b>		
Erythema annulare	2	0
Lichen planus	24	0
Lichen sclerosus	9	0
Parapsoriasis	5	0
Pityriasis alba	1	0
Pityriasis rosea	138	0
Pityriasis rubra pilaris	1	0
<b><i>Photosensitivity and photodermatosis conditions</i></b>		
Photosensitivity reaction	70	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	11	0
Hair disorder	1	0
Hair growth abnormal	10	0
Hair texture abnormal	7	0
Piloerection	29	0
Pseudofolliculitis	3	0
Trichorrhexis	3	0
<b><i>Pruritus NEC</i></b>		
Itching scar	10	0
Polymorphic eruption of pregnancy	1	0
Pruritus	6306	0
<b><i>Psoriatic conditions</i></b>		
Dermatitis psoriasiform	5	0
Guttate psoriasis	24	0
Nail psoriasis	2	0
Palmoplantar pustulosis	2	0
Psoriasis	238	0
Pustular psoriasis	3	0
Rebound psoriasis	1	0
<b><i>Purpura and related conditions</i></b>		
Ecchymosis	1	0
Henoch-Schonlein purpura	12	0
Petechiae	154	0
Purpura	60	0
<b><i>Pustular conditions</i></b>		
Acute generalised exanthematous pustulosis	2	0
<b><i>Rashes, eruptions and exanthems NEC</i></b>		
Butterfly rash	7	0
Rash	6587	1
Rash erythematous	1441	0
Rash macular	572	0
Rash maculo-papular	68	0
Rash morbilliform	49	0
Rash papular	401	0
Rash pruritic	1395	0



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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Rash scarlatiniform	1	0
Rash vesicular	85	0
Systemic lupus erythematosus rash	7	0
<b>Rosaceas</b>		
Rosacea	39	0
<b>Scaly conditions</b>		
Dandruff	5	0
Pityriasis	28	0
<b>Sebaceous gland disorders</b>		
Sebaceous glands overactivity	1	0
Seborrhoea	15	0
<b>Skin and subcutaneous conditions NEC</b>		
Cellulite	2	0
Cutaneous symptom	6	0
Reactive perforating collagenosis	1	0
Skin mass	28	0
<b>Skin and subcutaneous tissue ulcerations</b>		
Ischaemic skin ulcer	1	0
Mucocutaneous ulceration	1	0
Pyoderma gangrenosum	2	0
Scleroderma associated digital ulcer	1	0
Skin erosion	31	0
Skin ulcer	23	0
<b>Skin cysts and polyps</b>		
Dermal cyst	18	0
<b>Skin dystrophies</b>		
Keloid scar	3	0
Skin wrinkling	4	0
<b>Skin haemorrhages</b>		
Haemorrhage subcutaneous	15	0
Skin haemorrhage	21	0
<b>Skin hyperplasias and hypertrophies</b>		
Skin hypertrophy	2	0
<b>Skin hypoplasias and atrophies</b>		
Skin atrophy	3	0
Skin striae	8	0
<b>Skin injuries and mechanical dermatoses</b>		
Decubitus ulcer	3	0
Needle track marks	5	0
<b>Skin preneoplastic conditions NEC</b>		
Actinic keratosis	1	0
<b>Skin vascular conditions NEC</b>		
Angiodermatitis	1	0
Skin oedema	4	0
<b>Skin vasculitides</b>		
Capillaritis	4	0
Cutaneous vasculitis	15	0
Hypersensitivity vasculitis	1	0
Vasculitic rash	22	0
<b>Skin vasomotor conditions</b>		
Livedo reticularis	28	0
<b>Telangiectasia and related conditions</b>		
Spider naevus	1	0

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Telangiectasia	1	0
<b><i>Urticarias</i></b>		
Chronic spontaneous urticaria	13	0
Cold urticaria	9	0
Idiopathic urticaria	2	0
Mechanical urticaria	13	0
Solar urticaria	3	0
Urticaria	2263	0
Urticaria cholinergic	2	0
Urticaria chronic	40	0
Urticaria contact	1	0
Urticaria papular	6	0
Urticaria thermal	10	0
Urticarial vasculitis	7	0
<b>Skin disorders SOC TOTAL</b>	<b>33228</b>	<b>2</b>

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Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i><b>Age related issues</b></i>		
Infant	2	0
Menarche	3	0
Menopause	48	0
Postmenopause	5	0
<i><b>Criminal activity</b></i>		
Verbal abuse	1	0
<i><b>Dependents</b></i>		
Sick relative	6	0
<i><b>Dietary and nutritional issues</b></i>		
Feeding tube user	1	0
<i><b>Disability issues</b></i>		
Bedridden	33	0
Breast prosthesis user	3	0
Disability	2	0
Hearing disability	3	0
Housebound	1	0
Immobile	13	0
Impaired driving ability	5	0
Impaired work ability	22	0
Loss of personal independence in daily activities	46	0
Physical disability	5	0
Sight disability	13	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	2	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	2	0
Water pollution	2	0
<i><b>Pregnancy related circumstances</b></i>		
Breast feeding	17	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

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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>269</b>	<b>0</b>

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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	13	0
Wheat-free diet	1	0
<i><b>External ear therapeutic procedures</b></i>		
Ear irrigation	1	0
<i><b>Facial therapeutic procedures</b></i>		
Face lift	1	0
<i><b>Fertility and fertilisation interventions female</b></i>		
Endometrial scratching	1	0
Ovulation induction	2	0
<i><b>Gastric therapeutic procedures</b></i>		
Gastric operation	1	0
<i><b>Gastrointestinal therapeutic procedures NEC</b></i>		
Intestinal anastomosis	1	0
Prophylaxis of nausea and vomiting	16	0
<i><b>Gynaecological therapeutic procedures NEC</b></i>		
Menstrual cycle management	14	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	2	0

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
Surgical & medical procedures cont'd		
Hormone therapy	8	0
<b>Immunisations</b>		
COVID-19 immunisation	94	0
Immunisation	600	1
<b>Induced abortions</b>		
Abortion induced	1	0
<b>Joint therapeutic procedures</b>		
Joint injection	5	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	11	0
Limb operation	9	0
<b>Lip therapeutic procedures</b>		
Lip lesion excision	1	0
<b>Lymphoid tissue therapeutic procedures</b>		
Lymphadenectomy	2	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	3	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	3	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>		

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
Surgical & medical procedures cont'd		
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
<b>Spine and spinal cord therapeutic procedures</b>		
Spinal decompression	1	0
<b>Therapeutic bladder catheterisation</b>		
Bladder catheterisation	2	0
<b>Therapeutic procedures NEC</b>		
Abscess drainage	1	0
Anaphylaxis treatment	7	0
Bed rest	5	0
Fatigue management	1	0
Hospitalisation	14	0
Injection	54	0
Interchange of vaccine products	262	0
Localised alternating hot and cold therapy	2	0
Magnetic therapy	1	0
Mass excision	5	0
Medical procedure	1	0
Medication dilution	2	0
Physical fitness training	1	0
Product used for unknown indication	2	0
Promotion of wound healing	1	0
Specialist consultation	1	0
Stent placement	1	0
Stoma care	1	0
Therapeutic procedure	1	0
Therapy change	1	0
<b>Tracheal therapeutic procedures</b>		
Tracheostomy	1	0
<b>Uterine therapeutic procedures</b>		
Endometrial ablation	2	0
<b>Vascular therapeutic procedures NEC</b>		
Vasodilation procedure	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>1239</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i><b>Accelerated and malignant hypertension</b></i>		
Hypertensive crisis	14	0
Hypertensive urgency	2	0
Malignant hypertension	4	0
<i><b>Aneurysms and dissections non-site specific</b></i>		
Aneurysm	3	0
Aneurysm ruptured	1	0
Artery dissection	2	0
<i><b>Aortic aneurysms and dissections</b></i>		
Acute aortic syndrome	1	0
Aortic aneurysm	1	0
Aortic aneurysm rupture	1	1
Aortic dissection	1	0
<i><b>Aortic embolism and thrombosis</b></i>		
Aortic embolus	5	0
Aortic thrombosis	4	0
<i><b>Aortic infections and inflammations</b></i>		
Aortitis	1	0
<i><b>Aortic necrosis and vascular insufficiency</b></i>		
Aortic occlusion	1	0
<i><b>Arterial infections and inflammations</b></i>		
Arteritis	1	0
Giant cell arteritis	21	0
<i><b>Blood pressure disorders NEC</b></i>		
Blood pressure fluctuation	14	0
Labile blood pressure	3	0
<i><b>Bruising, ecchymosis and purpura</b></i>		
Achenbach syndrome	4	0
<i><b>Circulatory collapse and shock</b></i>		
CT hypotension complex	2	0
Circulatory collapse	85	0
Hypoperfusion	2	0
Hypovolaemic shock	2	1
Neurogenic shock	24	0
Peripheral circulatory failure	6	0
Shock	24	0
Shock symptom	3	0
<i><b>Haemorrhages NEC</b></i>		
Arterial haemorrhage	1	0
Bloody discharge	25	0
Haematoma	53	0
Haemorrhage	1399	2
Internal haemorrhage	13	0
Venous haemorrhage	2	0
<i><b>Lymphangiopathies</b></i>		
Lymphangiopathy	1	0
Lymphocele	7	0
Lymphorrhoea	2	0
Lymphostasis	1	0
<i><b>Lymphoedemas</b></i>		
Lymphoedema	241	0
<i><b>Non-site specific embolism and thrombosis</b></i>		
Arterial thrombosis	4	0



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Reaction Name	Total	Fatal
<b>Vascular disorders</b> <small>Vascular disorders cont'd</small>		
Embolism	64	0
Embolism arterial	2	0
Embolism venous	8	1
Microembolism	2	0
Thrombosis	518	11
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	4	0
Haemorrhagic infarction	1	0
Infarction	3	0
Ischaemia	11	0
Peripheral venous disease	2	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
Endothelial dysfunction	1	0
Haemodynamic instability	1	0
Superficial vein prominence	3	0
Vascular pain	43	0
Vascular wall hypertrophy	1	0
Vasodilatation	45	0
Vein discolouration	8	0
Vein disorder	8	0
Vein rupture	7	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	35	0
Deep vein thrombosis	347	1
Femoral artery embolism	1	0
Jugular vein thrombosis	4	0
Pelvic venous thrombosis	4	0
Peripheral artery thrombosis	2	0
Peripheral embolism	2	0
Subclavian vein thrombosis	4	0
Superficial vein thrombosis	30	0
Thrombophlebitis	27	0
<b><i>Peripheral vascular disorders NEC</i></b>		
Cyanosis	51	0
Erythromelalgia	2	0
Flushing	473	0
Hot flush	1259	0
Peripheral vascular disorder	2	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

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Reaction Name	Total	Fatal
<b>Vascular disorders</b> <small>Vascular disorders cont'd</small>		
Intermittent claudication	3	0
Ischaemic limb pain	2	0
Jugular vein occlusion	2	0
Peripheral arterial occlusive disease	2	0
Peripheral artery occlusion	1	0
Peripheral coldness	387	0
Peripheral ischaemia	12	0
Poor peripheral circulation	21	0
Raynaud's phenomenon	68	0
Subclavian vein occlusion	1	0
Vasoconstriction	2	0
<b>Phlebitis NEC</b>		
Phlebitis	37	0
Phlebitis superficial	9	0
<b>Site specific vascular disorders NEC</b>		
Aortic disorder	1	0
Aortic rupture	2	2
Inferior vena cava dilatation	1	0
Pallor	427	0
<b>Varicose veins NEC</b>		
Spider vein	7	0
Varicophlebitis	4	0
Varicose vein	39	0
<b>Vascular hypertensive disorders NEC</b>		
Diastolic hypertension	6	0
Essential hypertension	5	0
Hypertension	745	0
Labile hypertension	2	0
Orthostatic hypertension	2	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	457	1
Orthostatic hypotension	34	0
<b>Vasculitides NEC</b>		
Behcet's syndrome	5	0
Diffuse vasculitis	1	0
Granulomatosis with polyangiitis	2	0
MAGIC syndrome	2	0
Thromboangiitis obliterans	1	0
Vasculitis	53	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>7337</b>	<b>20</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>475033</b>	<b>720</b>
<b>TOTAL REPORTS</b>	<b>165379</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>720</b>