

## COVID-19 mRNA Pfizer- BioNTech Vaccine Analysis Print

Report Run Date: 29-Jul-2021  
Data Lock Date: 28-Jul-2021 18:30:14

All UK spontaneous reports received between 09/12/20 and 28/07/2021 for mRNA Pfizer/BioNTech vaccine

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

## Case Series Drug Analysis Print

### Name: COVID-19 mRNA Pfizer- BioNTech Vaccine Analysis Print

Report Run Date: 29-Jul-2021  
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 28-Jul-2021 18:30:14  
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<b><i>Anaemia deficiencies</i></b>		
Anaemia folate deficiency	1	0
Anaemia vitamin B12 deficiency	2	0
Deficiency anaemia	1	0
Iron deficiency anaemia	6	0
<b><i>Anaemias NEC</i></b>		
Anaemia	75	0
Anaemia macrocytic	1	0
Anaemia megaloblastic	1	0
Autoimmune anaemia	2	0
Microcytic anaemia	1	0
<b><i>Anaemias haemolytic NEC</i></b>		
Haemolytic anaemia	5	0
<b><i>Anaemias haemolytic immune</i></b>		
Autoimmune haemolytic anaemia	8	1
<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	28	0
Spontaneous haematoma	2	0
<b><i>Coagulation factor deficiencies</i></b>		
Acquired haemophilia	2	0
<b><i>Coagulopathies</i></b>		
Abnormal clotting factor	3	0
Antiphospholipid syndrome	5	0
Coagulopathy	14	1
Disseminated intravascular coagulation	2	0
Hypercoagulation	3	0
Thrombotic microangiopathy	2	0
<b><i>Eosinophilic disorders</i></b>		
Eosinophilia	12	0
<b><i>Haematological disorders</i></b>		
Blood disorder	2	0
Mast cell activation syndrome	4	0
Methaemoglobinaemia	1	0
<b><i>Haemolyses NEC</i></b>		
Haemolysis	6	0
Intravascular haemolysis	1	0
<b><i>Leukocytoses NEC</i></b>		
Leukocytosis	1	0
Lymphocytosis	5	0
Neutrophilia	6	0
<b><i>Leukopenias NEC</i></b>		
Leukopenia	3	0
Lymphopenia	3	0
<b><i>Lymphatic system disorders NEC</i></b>		
Abdominal lymphadenopathy	1	0
Hilar lymphadenopathy	2	0
Lymph node pain	1104	0
Lymphadenitis	105	0
Lymphadenopathy	7395	0
Lymphatic disorder	1	0

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<b>Blood disorders</b> Blood disorders cont'd		
Necrotic lymphadenopathy	3	0
Pseudolymphoma	9	0
Retroperitoneal lymphadenopathy	1	0
<b><i>Marrow depression and hypoplastic anaemias</i></b>		
Aplasia pure red cell	2	0
Hypoplastic anaemia	1	0
Myelosuppression	1	0
Pancytopenia	6	0
<b><i>Neutropenias</i></b>		
Autoimmune neutropenia	2	0
Neutropenia	34	0
<b><i>Platelet disorders NEC</i></b>		
Platelet anisocytosis	1	0
Platelet disorder	1	0
<b><i>Purpuras (excl thrombocytopenic)</i></b>		
Purpura non-thrombocytopenic	1	0
<b><i>Red blood cell abnormal findings NEC</i></b>		
Polychromasia	2	0
Red blood cell abnormality	2	0
<b><i>Spleen disorders</i></b>		
Spleen atrophy	1	0
Splenic infarction	2	0
Splenic thrombosis	1	0
Splenic vein thrombosis	1	0
Splenomegaly	9	0
<b><i>Thrombocytopenias</i></b>		
Immune thrombocytopenia	68	0
Thrombocytopenia	158	1
Thrombocytopenic purpura	4	0
Thrombotic thrombocytopenic purpura	5	0
<b><i>Thrombocytoses</i></b>		
Thrombocytosis	4	0
<b>Blood disorders SOC TOTAL</b>	<b>9137</b>	<b>3</b>

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<b>Cardiac disorders</b>		
<i><b>Cardiac conduction disorders</b></i>		
Atrioventricular block	8	1
Atrioventricular block complete	1	0
Atrioventricular block first degree	1	0
Atrioventricular block second degree	2	0
Bundle branch block	2	0
Bundle branch block right	1	0
<i><b>Cardiac disorders NEC</b></i>		
Acute cardiac event	3	0
Cardiac disorder	38	0
Cardiac dysfunction	1	0
Cardiovascular deconditioning	1	0
Cardiovascular disorder	4	0
Intracardiac thrombus	3	0
<i><b>Cardiac hypertensive complications</b></i>		
Hypertensive heart disease	1	0
<i><b>Cardiac infections and inflammations NEC</b></i>		
Carditis	1	0
<i><b>Cardiac signs and symptoms NEC</b></i>		
Cardiac discomfort	7	0
Cardiovascular symptom	1	0
Palpitations	2029	0
<i><b>Cardiac valve disorders NEC</b></i>		
Cardiac valve disease	1	0
Heart valve incompetence	1	0
<i><b>Cardiomyopathies</b></i>		
Cardiomyopathy	4	0
Congestive cardiomyopathy	4	0
Stress cardiomyopathy	2	0
<i><b>Coronary artery disorders NEC</b></i>		
Coronary artery disease	4	2
Coronary artery occlusion	2	0
Coronary artery thrombosis	1	0
<i><b>Endocarditis NEC</b></i>		
Endocarditis noninfective	1	1
<i><b>Heart failures NEC</b></i>		
Cardiac failure	49	6
Cardiac failure acute	2	0
Cardiac failure chronic	1	0
Cardiac failure congestive	3	1
Cardiogenic shock	4	1
Cardiopulmonary failure	1	1
<i><b>Ischaemic coronary artery disorders</b></i>		
Acute coronary syndrome	3	0
Acute myocardial infarction	17	1
Angina pectoris	108	0
Angina unstable	2	0
Arteriospasm coronary	1	0
Microvascular coronary artery disease	2	0
Myocardial infarction	155	27
Myocardial ischaemia	6	2
<i><b>Left ventricular failures</b></i>		
Acute left ventricular failure	1	1

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<b>Cardiac disorders</b> Cardiac disorders cont'd		
Left ventricular failure	5	2
<b>Mitral valvular disorders</b>		
Mitral valve incompetence	3	0
Mitral valve prolapse	1	0
<b>Myocardial disorders NEC</b>		
Cardiac amyloidosis	1	0
Cardiomegaly	11	1
Left atrial dilatation	1	0
Left ventricular dysfunction	5	0
Left ventricular enlargement	1	0
Left ventricular hypertrophy	1	0
Myocardial fibrosis	1	0
Myocardial haemorrhage	1	0
Myocardial oedema	3	0
Myocardial rupture	1	0
Right ventricular enlargement	1	0
Ventricular hypertrophy	1	0
<b>Noninfectious myocarditis</b>		
Myocarditis	149	1
<b>Noninfectious pericarditis</b>		
Pericarditis	129	1
<b>Pericardial disorders NEC</b>		
Pericardial effusion	17	0
Pericardial haemorrhage	3	3
Pericardial rub	1	0
<b>Rate and rhythm disorders NEC</b>		
Arrhythmia	85	0
Bradycardia	47	0
Bradycardia foetal	1	1
Cardiac flutter	236	0
Extrasystoles	92	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	12	0
Tachyarrhythmia	1	0
Tachycardia	580	0
Tachycardia paroxysmal	1	0
<b>Right ventricular failures</b>		
Cor pulmonale	1	0
<b>Supraventricular arrhythmias</b>		
Arrhythmia supraventricular	8	0
Atrial fibrillation	145	0
Atrial flutter	12	0
Atrial tachycardia	4	0
Nodal arrhythmia	1	0
Sinus arrest	1	0
Sinus arrhythmia	2	0
Sinus bradycardia	6	0
Sinus tachycardia	40	0
Supraventricular extrasystoles	1	0
Supraventricular tachycardia	29	0
<b>Tricuspid valvular disorders</b>		
Tricuspid valve incompetence	1	0
<b>Ventricular arrhythmias and cardiac arrest</b>		

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<b>Cardiac disorders</b> Cardiac disorders cont'd		
Cardiac arrest	80	32
Cardio-respiratory arrest	1	1
Pulseless electrical activity	3	0
Ventricular arrhythmia	4	0
Ventricular extrasystoles	12	0
Ventricular fibrillation	6	1
Ventricular tachycardia	10	0
<b>Cardiac disorders SOC TOTAL</b>	<b>4238</b>	<b>87</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	10	0
<i>Cardiac septal defects congenital</i>		
Hypertrophic cardiomyopathy	1	0
<i>Central nervous system disorders congenital NEC</i>		
Spina bifida	1	0
<i>Cerebellar disorders congenital</i>		
Arnold-Chiari malformation	1	0
Hereditary ataxia	1	0
<i>Cerebral disorders congenital</i>		
Cerebral palsy	2	0
<i>Chemically-induced congenital syndromes</i>		
Foetal warfarin syndrome	1	0
<i>Coagulation disorders congenital</i>		
Haemophilia	1	0
<i>Congenital disorders NEC</i>		
Foetal malformation	1	0
Young's syndrome	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	2	0
<i>External ear disorders congenital</i>		
Anotia	1	0
<i>Gastrointestinal tract disorders congenital NEC</i>		
Gastroschisis	1	0
<i>Great vessel disorders congenital</i>		
Transposition of the great vessels	1	0
<i>Haematological disorders congenital NEC</i>		
Amegakaryocytic thrombocytopenia	1	0
Neonatal alloimmune thrombocytopenia	1	0
<i>Haemoglobinopathies congenital</i>		
Congenital methaemoglobinaemia	1	0
<i>Lymphatic system disorders congenital</i>		
Cystic lymphangioma	3	0
<i>Male reproductive tract disorders congenital</i>		
Cryptorchism	1	0
Micropenis	2	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Developmental hip dysplasia	1	0
<i>Musculoskeletal and connective tissue disorders of spine congenital</i>		
Brachyolmia	1	0
<i>Musculoskeletal disorders congenital NEC</i>		
Congenital multiplex arthrogryposis	1	0
<i>Neurological disorders congenital NEC</i>		
Familial hemiplegic migraine	2	0
Familial periodic paralysis	1	0
Moebius II syndrome	1	0
Tourette's disorder	2	0
<i>Ocular disorders congenital NEC</i>		
Colour blindness	2	0
<i>Palate disorders congenital</i>		
Cleft lip and palate	1	0
<i>Peripheral nervous system disorders congenital NEC</i>		
Hereditary neuropathy with liability to pressure palsies	1	0

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Reaction Name	Total	Fatal
<b>Congenital disorders</b> Congenital disorders cont'd		
<i>Pulmonary and bronchial disorders congenital</i>		
Congenital cystic lung	1	0
<i>Retinal disorders congenital</i>		
Retinitis pigmentosa	1	0
<i>Skin and subcutaneous tissue disorders congenital NEC</i>		
Acral peeling skin syndrome	1	0
<i>Tongue disorders congenital</i>		
Ankyloglossia congenital	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>51</b>	<b>0</b>



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<b>Ear disorders</b>		
<i><b>Ear disorders NEC</b></i>		
Ear canal erythema	1	0
Ear congestion	20	0
Ear discomfort	72	0
Ear disorder	14	0
Ear haemorrhage	8	0
Ear pain	693	0
Ear pruritus	8	0
Ear swelling	23	0
Otorrhoea	3	0
<i><b>Eustachian tube disorders</b></i>		
Eustachian tube disorder	3	0
Eustachian tube dysfunction	7	0
Eustachian tube obstruction	2	0
<i><b>External ear disorders NEC</b></i>		
Auricular swelling	1	0
Excessive cerumen production	4	0
External ear pain	2	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	174	0
Deafness bilateral	6	0
Deafness neurosensory	12	0
Deafness transitory	4	0
Deafness unilateral	25	0
Hypoacusis	132	0
Sudden hearing loss	29	0
<i><b>Hyperacusia</b></i>		
Hyperacusis	37	0
Misophonia	3	0
<i><b>Inner ear disorders NEC</b></i>		
Acute vestibular syndrome	1	0
Inner ear disorder	9	0
Meniere's disease	8	0
Vestibular disorder	8	0
<i><b>Inner ear infections and inflammations</b></i>		
Inner ear inflammation	5	0
<i><b>Inner ear signs and symptoms</b></i>		
Motion sickness	38	0
Tinnitus	1378	0
Vertigo	976	0
Vertigo labyrinthine	9	0
Vertigo positional	60	0
<i><b>Mastoid disorders</b></i>		
Mastoid effusion	1	0
<i><b>Middle ear disorders NEC</b></i>		
Middle ear disorder	3	0

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Reaction Name		Total	Fatal
<b>Ear disorders</b>	Ear disorders cont'd		
Middle ear effusion		1	0
<i>Middle ear infections and inflammations</i>			
Middle ear inflammation		1	0
<b>Ear disorders SOC TOTAL</b>		<b>3794</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	1	0
Thyroiditis	9	0
Thyroiditis acute	1	0
Thyroiditis subacute	2	0
<i><b>Adrenal cortical hypofunctions</b></i>		
Addison's disease	1	0
Adrenocortical insufficiency acute	9	0
<i><b>Adrenal gland disorders NEC</b></i>		
Adrenal haemorrhage	2	0
<i><b>Anterior pituitary hyperfunction</b></i>		
Pituitary-dependent Cushing's syndrome	1	0
<i><b>Anterior pituitary hypofunction</b></i>		
Hypopituitarism	1	0
<i><b>Endocrine abnormalities of puberty</b></i>		
Delayed menarche	3	0
Premature menarche	13	0
<i><b>Female gonadal function disorders</b></i>		
Anovulatory cycle	27	0
Ovulation delayed	18	0
<i><b>Thyroid disorders NEC</b></i>		
Autoimmune thyroid disorder	1	0
Goitre	10	0
Thyroid disorder	6	0
Thyroid mass	1	0
Thyroid pain	3	0
<i><b>Thyroid hyperfunction disorders</b></i>		
Basedow's disease	3	0
Hyperthyroidism	19	0
Thyrotoxic crisis	3	0
<i><b>Thyroid hypofunction disorders</b></i>		
Autoimmune hypothyroidism	1	0
Hypothyroidism	20	0
Myxoedema	1	0
<b>Endocrine disorders SOC TOTAL</b>	<b>156</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i><b>Amblyopic vision impairment</b></i>		
Amblyopia	5	0
<i><b>Cataract conditions</b></i>		
Cataract	10	0
<i><b>Choroid and vitreous haemorrhages and vascular disorders</b></i>		
Choroidal haemorrhage	1	0
Choroidal neovascularisation	1	0
Vitreous haemorrhage	3	0
<i><b>Choroid and vitreous structural change, deposit and degeneration</b></i>		
Chorioretinopathy	2	0
Vitreous detachment	16	0
Vitreous floaters	54	0
<i><b>Colour blindness (incl acquired)</b></i>		
Dyschromatopsia	5	0
<i><b>Conjunctival and corneal bleeding and vascular disorders</b></i>		
Conjunctival haemorrhage	31	0
<i><b>Conjunctival infections, irritations and inflammations</b></i>		
Conjunctival hyperaemia	2	0
Conjunctival irritation	1	0
Conjunctival oedema	3	0
<i><b>Corneal infections, oedemas and inflammations</b></i>		
Keratitis	6	0
Ulcerative keratitis	4	0
<i><b>Eyelid movement disorders</b></i>		
Blepharospasm	100	0
Excessive eye blinking	4	0
Eyelid function disorder	3	0
Eyelid myokymia	3	0
Eyelid ptosis	37	0
Paralytic lagophthalmos	2	0
<i><b>Glaucomas (excl congenital)</b></i>		
Angle closure glaucoma	2	0
Glaucoma	5	0
<i><b>Iris and ciliary body structural change, deposit and degeneration</b></i>		
Eye colour change	2	0
<i><b>Iris and uveal tract infections, irritations and inflammations</b></i>		
Autoimmune uveitis	1	0
Iridocyclitis	9	0
Iritis	5	0
Uveitis	27	0
<i><b>Lacrimation disorders</b></i>		
Dry eye	104	0
Lacrimation increased	97	0
<i><b>Lid bleeding and vascular disorders</b></i>		
Eyelid bleeding	1	0
<i><b>Lid, lash and lacrimal infections, irritations and inflammations</b></i>		
Blepharitis	7	0
Chalazion	6	0
Eczema eyelids	4	0
Erythema of eyelid	5	0
Eyelid cyst	4	0
Eyelid irritation	2	0
Eyelid margin crusting	3	0

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<b>Eye disorders</b> Eye disorders cont'd		
Eyelid oedema	3	0
Eyelid rash	12	0
Swelling of eyelid	93	0
<b>Lid, lash and lacrimal structural disorders</b>		
Dermatochalasis	1	0
Eyelash changes	1	0
Eyelid exfoliation	2	0
Eyelid skin dryness	2	0
Floppy eyelid syndrome	1	0
Growth of eyelashes	2	0
Lagophthalmos	2	0
<b>Ocular bleeding and vascular disorders NEC</b>		
Eye haematoma	4	0
Eye haemorrhage	20	0
Ocular vascular disorder	1	0
Ophthalmic vein thrombosis	1	0
<b>Ocular disorders NEC</b>		
Dark circles under eyes	6	0
Eye disorder	22	0
Eye oedema	9	0
Eye pain	741	0
Eye swelling	358	0
Eye symptom	8	0
Eye ulcer	2	0
Eyelid disorder	10	0
Eyelid pain	9	0
Eyelids pruritus	5	0
Ocular discomfort	23	0
Periorbital oedema	16	0
Periorbital pain	1	0
Periorbital swelling	96	0
Retinal disorder	1	0
Vitreous disorder	1	0
<b>Ocular infections, inflammations and associated manifestations</b>		
Eye allergy	7	0
Eye discharge	16	0
Eye inflammation	19	0
Eye irritation	76	0
Eye pruritus	186	0
Limbal swelling	2	0
Ocular hyperaemia	157	0
<b>Ocular nerve and muscle disorders</b>		
Binocular eye movement disorder	1	0
Extraocular muscle disorder	1	0
Extraocular muscle paresis	1	0
Eye movement disorder	21	0
Gaze palsy	1	0
Ocular myasthenia	1	0
Ophthalmoplegia	3	0
Strabismus	5	0
<b>Ocular sensation disorders</b>		
Abnormal sensation in eye	12	0
Asthenopia	115	0

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<b>Eye disorders</b> Eye disorders cont'd		
Eye paraesthesia	1	0
Foreign body sensation in eyes	16	0
Hypoaesthesia eye	13	0
Photophobia	301	0
<b>Optic disc abnormalities NEC</b>		
Papilloedema	4	0
<b>Optic nerve bleeding and vascular disorders</b>		
Optic disc haemorrhage	1	0
Optic ischaemic neuropathy	2	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	17	0
Pupil fixed	2	0
Pupils unequal	7	0
<b>Refractive and accommodative disorders</b>		
Altered visual depth perception	2	0
Astigmatism	1	0
Myopia	1	0
<b>Retinal bleeding and vascular disorders (excl retinopathy)</b>		
Retinal artery occlusion	7	0
Retinal artery thrombosis	1	0
Retinal haemorrhage	5	0
Retinal vein occlusion	24	0
Retinal vein thrombosis	2	0
<b>Retinal structural change, deposit and degeneration</b>		
Macular degeneration	2	0
Macular hole	2	0
Macular rupture	1	0
Maculopathy	1	0
Neovascular age-related macular degeneration	2	0
Retinal detachment	3	0
Retinal tear	2	0
Retinal toxicity	3	0
<b>Retinal, choroid and vitreous infections and inflammations</b>		
Birdshot chorioretinopathy	1	0
Cystoid macular oedema	1	0
Macular oedema	3	0
Retinal vasculitis	3	0
<b>Retinopathies NEC</b>		
Acute macular outer retinopathy	1	0
Retinal exudates	2	0
Retinopathy	1	0
<b>Scleral infections, irritations and inflammations</b>		
Episcleritis	7	0
Scleritis	2	0
<b>Scleral structural change, deposit and degeneration</b>		
Scleral discolouration	2	0
<b>Visual colour distortions</b>		
Chloropsia	3	0

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<b>Eye disorders</b> Eye disorders cont'd		
Cyanopsia	1	0
Erythropsia	2	0
Xanthopsia	1	0
<b>Visual disorders NEC</b>		
Charles Bonnet syndrome	1	0
Diplopia	124	0
Glare	1	0
Halo vision	6	0
Metamorphopsia	15	0
Oscillopsia	2	0
Photopsia	91	0
Scintillating scotoma	3	0
Vision blurred	829	0
Visual brightness	3	0
Visual snow syndrome	3	0
<b>Visual field disorders</b>		
Visual field defect	14	0
<b>Visual impairment and blindness (excl colour blindness)</b>		
Amaurosis fugax	2	0
Blindness	86	0
Blindness transient	9	0
Blindness unilateral	10	0
Central vision loss	2	0
Sudden visual loss	3	0
Visual acuity reduced	16	0
Visual acuity reduced transiently	1	0
Visual impairment	236	0
<b>Visual pathway disorders</b>		
Optic nerve disorder	1	0
<b>Eye disorders SOC TOTAL</b>	<b>4570</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: COVID-19 mRNA Pfizer- BioNTech Vaccine Analysis Print

Report Run Date: 29-Jul-2021  
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 28-Jul-2021 18:30:14  
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Abdominal findings abnormal</i>		
Abdominal mass	1	0
Gastrointestinal sounds abnormal	14	0
<i>Abdominal hernias NEC</i>		
Abdominal hernia	1	0
<i>Abdominal wall conditions NEC</i>		
Abdominal wall haematoma	1	0
<i>Acute and chronic pancreatitis</i>		
Obstructive pancreatitis	1	0
Pancreatitis	9	0
Pancreatitis acute	9	0
Pancreatitis necrotising	1	0
<i>Anal and rectal disorders NEC</i>		
Anal fissure	2	0
Anal sphincter atony	1	0
<i>Anal and rectal pains</i>		
Proctalgia	8	0
<i>Anal and rectal signs and symptoms</i>		
Anal hypoaesthesia	1	0
Anal spasm	1	0
Anorectal discomfort	3	0
Anorectal swelling	1	0
Rectal discharge	1	0
Rectal tenesmus	1	0
<i>Benign oral cavity neoplasms</i>		
Mouth cyst	4	0
Tongue cyst	4	0
<i>Colitis (excl infective)</i>		
Autoimmune colitis	1	0
Colitis	31	1
Colitis ischaemic	1	0
Colitis microscopic	1	0
Colitis ulcerative	51	0
Crohn's disease	31	0
Eosinophilic colitis	1	0
Inflammatory bowel disease	2	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	1	0
<i>Dental disorders NEC</i>		
Teeth brittle	1	0
Teething	4	0
Tooth disorder	2	0
<i>Dental pain and sensation disorders</i>		
Dental discomfort	5	0
Dental paraesthesia	10	0
Hyperaesthesia teeth	25	0
Toothache	111	0
<i>Dental surface disorders</i>		
Tooth discolouration	4	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	5	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	3814	2



# Case Series Drug Analysis Print

## Name: COVID-19 mRNA Pfizer- BioNTech Vaccine Analysis Print

Report Run Date: 29-Jul-2021  
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 28-Jul-2021 18:30:14  
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
Diarrhoea haemorrhagic	20	0
<b>Diverticula</b>		
Diverticulum	4	0
Diverticulum intestinal	1	0
<b>Duodenal and small intestinal stenosis and obstruction</b>		
Small intestinal obstruction	1	0
<b>Duodenal ulcers and perforation</b>		
Duodenal ulcer haemorrhage	1	0
Duodenal ulcer perforation	3	0
<b>Dyspeptic signs and symptoms</b>		
Dyspepsia	279	0
Epigastric discomfort	12	0
Eructation	33	0
<b>Faecal abnormalities NEC</b>		
Abnormal faeces	12	0
Faecaloma	2	0
Faeces discoloured	38	0
Faeces hard	1	0
Faeces pale	3	0
Faeces soft	10	0
Mucous stools	6	0
<b>Flatulence, bloating and distension</b>		
Abdominal distension	327	0
Aerophagia	3	0
Flatulence	130	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	6	0
<b>Gastritis (excl infective)</b>		
Chronic gastritis	2	0
Gastritis	32	0
Reflux gastritis	4	0
<b>Gastrointestinal and abdominal pains (excl oral and throat)</b>		
Abdominal migraine	2	0
Abdominal pain	973	0
Abdominal pain lower	85	0
Abdominal pain upper	1613	0
Abdominal rigidity	16	0
Abdominal tenderness	9	0
Gastrointestinal pain	93	0
Oesophageal pain	4	0
<b>Gastrointestinal atonic and hypomotility disorders NEC</b>		
Constipation	173	0
Duodenogastric reflux	3	0
Gastric dilatation	6	0
Gastrooesophageal reflux disease	86	0
Impaired gastric emptying	5	0
Infrequent bowel movements	2	0
Intestinal pseudo-obstruction	2	0
<b>Gastrointestinal disorders NEC</b>		

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
Gastrointestinal disorders cont'd		
Food poisoning	2	0
Functional gastrointestinal disorder	6	0
Gastric disorder	6	0
Gastrointestinal disorder	12	0
Stomach mass	3	0
<b>Gastrointestinal dyskinetic disorders</b>		
Bowel movement irregularity	2	0
Change of bowel habit	4	0
Dyschezia	2	0
Gastrointestinal motility disorder	1	0
Oesophageal achalasia	1	0
<b>Gastrointestinal fistulae</b>		
Diverticular fistula	1	0
<b>Gastrointestinal inflammatory disorders NEC</b>		
Duodenitis	1	0
Enteritis	4	0
Epiploic appendagitis	2	0
Gastrointestinal inflammation	3	0
Intestinal angioedema	2	0
<b>Gastrointestinal mucosal dystrophies and secretion disorders</b>		
Hyperchlorhydria	4	0
<b>Gastrointestinal signs and symptoms NEC</b>		
Abdominal discomfort	443	0
Abdominal symptom	1	0
Acute abdomen	4	0
Anal incontinence	17	0
Breath odour	15	0
Dysphagia	150	1
Odynophagia	24	0
<b>Gastrointestinal spastic and hypermotility disorders</b>		
Cardiospasm	1	0
Defaecation urgency	8	0
Frequent bowel movements	21	0
Irritable bowel syndrome	58	0
Oesophageal spasm	3	0
Pylorospasm	1	0
<b>Gastrointestinal stenosis and obstruction NEC</b>		
Intestinal obstruction	2	0
Neonatal intestinal obstruction	1	0
<b>Gastrointestinal vascular malformations</b>		
Gastric antral vascular ectasia	5	0
<b>Gastrointestinal vascular occlusion and infarction</b>		
Intestinal ischaemia	5	2
Mesenteric vein thrombosis	4	0
Omental infarction	1	0
Thrombosis mesenteric vessel	1	0
Visceral venous thrombosis	1	0
<b>Gingival disorders, signs and symptoms NEC</b>		
Gingival blister	11	0
Gingival discomfort	2	0
Gingival disorder	3	0
Gingival erythema	2	0
Gingival oedema	1	0

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Gingival pain	78	0
Gingival pruritus	1	0
Gingival swelling	26	0
Gingival ulceration	1	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	5	0
<b>Gingival haemorrhages</b>		
Gingival bleeding	46	0
<b>Haemorrhoids and gastrointestinal varices (excl oesophageal)</b>		
Gastric varices	1	0
Haemorrhoids	23	0
Haemorrhoids thrombosed	1	0
<b>Intestinal haemorrhages</b>		
Anal haemorrhage	13	0
Intestinal haemorrhage	1	0
Rectal haemorrhage	48	0
Small intestinal haemorrhage	6	0
<b>Intestinal ulcers and perforation NEC</b>		
Intestinal perforation	4	2
Large intestine perforation	1	0
<b>Malabsorption syndromes</b>		
Bile acid malabsorption	1	0
Coeliac disease	8	0
Steatorrhoea	4	0
<b>Nausea and vomiting symptoms</b>		
Discoloured vomit	10	0
Infantile vomiting	4	0
Nausea	10093	1
Regurgitation	1	0
Retching	74	0
Vomiting	2945	1
Vomiting projectile	42	0
<b>Non-mechanical ileus</b>		
Ileus paralytic	1	0
<b>Non-site specific gastrointestinal haemorrhages</b>		
Gastrointestinal haemorrhage	12	0
Haematemesis	26	2
Haematochezia	40	0
Melaena	8	0
Upper gastrointestinal haemorrhage	2	0
<b>Oesophageal stenosis and obstruction</b>		
Oesophageal stenosis	2	0
<b>Oesophagitis (excl infective)</b>		
Eosinophilic oesophagitis	1	0
Oesophagitis	2	0
<b>Oral dryness and saliva altered</b>		
Aptyalism	2	0
Dry mouth	381	0
Lip dry	32	0
Saliva altered	4	0
Salivary hypersecretion	37	0
<b>Oral soft tissue disorders NEC</b>		
Angina bullosa haemorrhagica	1	0

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
Gastrointestinal disorders cont'd		
Chapped lips	17	0
Cheilitis	20	0
Enlarged uvula	12	0
Leukoplakia oral	1	0
Lip blister	21	0
Lip disorder	4	0
Oral disorder	8	0
Oral lichen planus	8	0
Oral mucosal hypertrophy	1	0
Oral papule	1	0
Uvulitis	2	0
<b>Oral soft tissue haemorrhages</b>		
Mouth haemorrhage	10	0
Oral blood blister	10	0
Oral purpura	2	0
<b>Oral soft tissue infections</b>		
Angular cheilitis	1	0
<b>Oral soft tissue signs and symptoms</b>		
Anaesthesia oral	1	0
Burning mouth syndrome	5	0
Coating in mouth	1	0
Hypoaesthesia oral	373	0
Lip discolouration	7	0
Lip erythema	2	0
Lip exfoliation	5	0
Lip pain	41	0
Lip pruritus	11	0
Lip scab	1	0
Oral discomfort	64	0
Oral dysaesthesia	1	0
Oral mucosal blistering	12	0
Oral mucosal discolouration	1	0
Oral mucosal eruption	11	0
Oral mucosal erythema	5	0
Oral mucosal exfoliation	7	0
Oral mucosal roughening	3	0
Oral pain	131	0
Oral pruritus	18	0
Paraesthesia oral	752	0
Pigmentation lip	1	0
<b>Oral soft tissue swelling and oedema</b>		
Lip oedema	3	0
Lip swelling	541	0
Mouth swelling	68	0
Oedema mouth	4	0
Palatal oedema	2	0
Palatal swelling	1	0
<b>Peptic ulcers and perforation</b>		
Peptic ulcer	1	0
Peptic ulcer haemorrhage	9	0
<b>Peritoneal and retroperitoneal disorders</b>		
Ascites	1	0
<b>Peritoneal and retroperitoneal fibrosis and adhesions</b>		

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Abdominal adhesions	1	0
<b><i>Peritoneal and retroperitoneal haemorrhages</i></b>		
Haemoperitoneum	1	0
Retroperitoneal haemorrhage	1	1
<b><i>Rectal inflammations NEC</i></b>		
Proctitis	1	0
Proctitis ulcerative	1	0
<b><i>Salivary gland disorders NEC</i></b>		
Salivary gland disorder	1	0
Salivary gland pain	12	0
<b><i>Salivary gland enlargements</i></b>		
Parotid gland enlargement	8	0
Salivary gland enlargement	3	0
Submaxillary gland enlargement	6	0
<b><i>Salivary gland infections and inflammations</i></b>		
Noninfective sialoadenitis	1	0
<b><i>Stomatitis and ulceration</i></b>		
Aphthous ulcer	34	0
Lip ulceration	14	0
Mouth ulceration	324	0
Oral mucosa erosion	1	0
Palatal ulcer	1	0
Stomatitis	47	0
<b><i>Tongue disorders</i></b>		
Glossitis	14	0
Plicated tongue	3	0
Tongue disorder	30	0
Tongue haemorrhage	2	0
Tongue ulceration	26	0
Trichoglossia	4	0
<b><i>Tongue signs and symptoms</i></b>		
Glossodynia	161	0
Scalloped tongue	5	0
Stiff tongue	3	0
Swollen tongue	378	0
Tongue blistering	15	0
Tongue coated	15	0
Tongue discolouration	28	0
Tongue discomfort	32	0
Tongue dry	12	0
Tongue eruption	9	0
Tongue erythema	7	0
Tongue exfoliation	1	0
Tongue movement disturbance	5	0
Tongue oedema	19	0
Tongue pruritus	1	0
Tongue rough	2	0
Tongue spasm	8	0
<b><i>Tooth missing</i></b>		
Tooth loss	4	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>26446</b>	<b>14</b>

## Case Series Drug Analysis Print

### Name: COVID-19 mRNA Pfizer- BioNTech Vaccine Analysis Print

Report Run Date: 29-Jul-2021  
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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i><b>Administration site reactions NEC</b></i>		
Administration site bruise	5	0
Administration site erythema	3	0
Administration site extravasation	3	0
Administration site haematoma	3	0
Administration site inflammation	1	0
Administration site irritation	1	0
Administration site joint discomfort	1	0
Administration site joint movement impairment	1	0
Administration site nerve damage	1	0
Administration site pain	12	0
Administration site rash	3	0
Administration site swelling	2	0
Administration site urticaria	1	0
Administration site warmth	2	0
Puncture site bruise	22	0
Puncture site pain	5	0
Puncture site reaction	1	0
Puncture site swelling	2	0
Vessel puncture site bruise	2	0
Vessel puncture site erythema	1	0
Vessel puncture site pain	1	0
<i><b>Adverse effect absent</b></i>		
No adverse event	13	0
<i><b>Application and instillation site reactions</b></i>		
Application site acne	2	0
Application site bruise	6	0
Application site burn	1	0
Application site erythema	9	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	1	0
Application site pain	12	0
Application site pruritus	4	0
Application site rash	2	0
Application site reaction	1	0
Application site swelling	2	0
Application site vesicles	5	0
Instillation site warmth	4	0
<i><b>Asthenic conditions</b></i>		
Asthenia	1235	1
Chronic fatigue syndrome	57	0
Decreased activity	5	0
Fatigue	15987	0
Malaise	3569	0
Sluggishness	11	0
<i><b>Body temperature altered</b></i>		
Hyperthermia	5	0
Hypothermia	19	0

## Case Series Drug Analysis Print

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Report Run Date: 29-Jul-2021  
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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Temperature regulation disorder	8	0
<b>Breast complications associated with device</b>		
Capsular contracture associated with breast implant	1	0
<b>Cardiac complications associated with device</b>		
Prosthetic cardiac valve thrombosis	1	0
<b>Complications associated with device NEC</b>		
Capsular contracture associated with implant	1	0
Complication of device removal	1	0
Injury associated with device	2	0
Medical device pain	1	0
Medical device site swelling	1	0
Phantom shocks	1	0
<b>Death and sudden death</b>		
Brain death	2	1
Clinical death	1	1
Death	128	128
Sudden death	25	25
<b>Febrile disorders</b>		
Hyperpyrexia	7	0
Pyrexia	10375	0
<b>Feelings and sensations NEC</b>		
Chills	6729	0
Feeling abnormal	1044	0
Feeling cold	820	0
Feeling drunk	61	0
Feeling hot	805	0
Feeling jittery	16	0
Feeling of body temperature change	225	0
Hangover	53	0
Hunger	30	0
Sensation of blood flow	1	0
Sensation of foreign body	38	0
Temperature intolerance	27	0
Thirst	244	0
<b>Fibrosis NEC</b>		
Fibrosis	1	0
<b>Gait disturbances</b>		
Gait disturbance	125	0
Gait inability	47	0
Loss of control of legs	11	0
<b>General signs and symptoms NEC</b>		
Adhesion	1	0
Chronic disease	1	0
Condition aggravated	123	0
Crepitations	1	0
Crying	100	0
Deformity	2	0
Discharge	7	0
Disease progression	2	0
Disease recurrence	23	0
Effusion	2	0
Energy increased	14	0
Exercise tolerance decreased	11	0

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Foaming at mouth	1	0
General physical health deterioration	14	1
General symptom	2	0
Glassy eyes	3	0
High-pitched crying	2	0
Illness	1238	0
Induration	11	0
Influenza like illness	1647	0
Irritability postvaccinal	2	0
Local reaction	67	0
Moaning	2	0
Multiple organ dysfunction syndrome	5	3
Nonspecific reaction	1	0
Organ failure	1	1
Perforation	2	0
Peripheral swelling	2421	0
Pre-existing condition improved	8	0
Prolapse	1	0
Screaming	16	0
Secretion discharge	10	0
Swelling	1898	0
Swelling face	591	0
Symptom recurrence	1	0
<b>Implant and catheter site reactions</b>		
Implant site discolouration	2	0
Implant site pain	1	0
Implant site rash	1	0
Implant site swelling	1	0
Implant site urticaria	1	0
Implant site warmth	1	0
<b>Inflammations</b>		
Granuloma	1	0
Inflammation	273	0
Papillitis	1	0
Serositis	1	0
Systemic inflammatory response syndrome	2	0
<b>Infusion site reactions</b>		
Infusion site coldness	1	0
Infusion site joint pain	2	0
Infusion site mass	1	0
Infusion site pain	1	0
Infusion site swelling	1	0
Infusion site urticaria	1	0
Infusion site warmth	1	0
<b>Injection site reactions</b>		
Injected limb mobility decreased	23	0
Injection site bruising	50	0
Injection site coldness	1	0
Injection site cyst	2	0
Injection site discolouration	5	0
Injection site discomfort	9	0
Injection site erythema	274	0
Injection site haemorrhage	6	0



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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Injection site hypersensitivity	1	0
Injection site hypoaesthesia	8	0
Injection site indentation	5	0
Injection site induration	3	0
Injection site inflammation	27	0
Injection site joint discomfort	1	0
Injection site joint erythema	1	0
Injection site joint movement impairment	1	0
Injection site joint pain	12	0
Injection site lymphadenopathy	1	0
Injection site macule	1	0
Injection site mass	359	0
Injection site movement impairment	1	0
Injection site necrosis	3	0
Injection site oedema	11	0
Injection site pain	2218	0
Injection site paraesthesia	11	0
Injection site pruritus	134	0
Injection site rash	110	0
Injection site reaction	21	0
Injection site scab	2	0
Injection site scar	4	0
Injection site swelling	224	0
Injection site urticaria	19	0
Injection site vesicles	8	0
Injection site warmth	138	0
<b>Interactions</b>		
Alcohol interaction	2	0
Drug interaction	18	0
Inhibitory drug interaction	3	0
<b>Mass conditions NEC</b>		
Cyst	26	0
Mass	45	0
Nodule	27	0
<b>Mucosal findings abnormal</b>		
Mucosa vesicle	1	0
Mucosal dryness	1	0
Mucosal haemorrhage	9	0
Mucosal inflammation	2	0
Oedema mucosal	1	0
Polyp	2	0
<b>Necrosis NEC</b>		
Fat necrosis	2	0
Necrosis	3	0
<b>Oedema NEC</b>		
Face oedema	25	0
Generalised oedema	2	0
Localised oedema	15	0
Oedema	47	0
Oedema peripheral	64	0
<b>Pain and discomfort NEC</b>		
Axillary pain	1817	0
Chest discomfort	1064	0

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Chest pain	2278	1
Discomfort	278	0
Facial discomfort	14	0
Facial pain	156	0
Inflammatory pain	7	0
Non-cardiac chest pain	19	0
Pain	5835	0
Suprapubic pain	1	0
Tenderness	476	0
Visceral pain	1	0
<b>Therapeutic and nontherapeutic responses</b>		
Adverse drug reaction	34	1
Adverse event	3	0
Adverse food reaction	1	0
Adverse reaction	2	0
Drug ineffective	176	1
Drug intolerance	2	0
Immediate post-injection reaction	2	0
Inadequate analgesia	7	0
No reaction on previous exposure to drug	36	0
Product intolerance	1	0
Therapeutic product effect delayed	2	0
Therapeutic product effect increased	1	0
Therapeutic product ineffective	2	0
Therapeutic response decreased	2	0
Therapeutic response unexpected	58	0
Treatment failure	6	0
Vaccination failure	8	0
<b>Trophic disorders</b>		
Atrophy	1	0
Calcinosis	1	0
Hyperplasia	1	0
<b>Ulcers NEC</b>		
Ulcer	18	0
Ulcer haemorrhage	1	0
<b>Vaccination site reactions</b>		
Extensive swelling of vaccinated limb	9	0
Shoulder injury related to vaccine administration	17	0
Vaccination site bruising	88	0
Vaccination site coldness	2	0
Vaccination site cyst	4	0
Vaccination site dermatitis	1	0
Vaccination site discolouration	11	0
Vaccination site discomfort	37	0
Vaccination site dryness	1	0
Vaccination site eczema	1	0
Vaccination site erythema	459	0
Vaccination site granuloma	1	0
Vaccination site haematoma	1	0
Vaccination site haemorrhage	14	0
Vaccination site hypersensitivity	2	0
Vaccination site hypoaesthesia	13	0
Vaccination site induration	64	0

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Vaccination site inflammation	47	0
Vaccination site irritation	10	0
Vaccination site joint discomfort	2	0
Vaccination site joint erythema	7	0
Vaccination site joint inflammation	1	0
Vaccination site joint movement impairment	16	0
Vaccination site joint pain	26	0
Vaccination site joint swelling	3	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	3	0
Vaccination site macule	1	0
Vaccination site mass	190	0
Vaccination site movement impairment	61	0
Vaccination site nerve damage	1	0
Vaccination site nodule	2	0
Vaccination site oedema	3	0
Vaccination site pain	1656	0
Vaccination site paraesthesia	4	0
Vaccination site phlebitis	1	0
Vaccination site pruritus	119	0
Vaccination site rash	101	0
Vaccination site reaction	27	0
Vaccination site scab	2	0
Vaccination site scar	1	0
Vaccination site swelling	440	0
Vaccination site ulcer	1	0
Vaccination site urticaria	10	0
Vaccination site vesicles	6	0
Vaccination site warmth	215	0
<b>Vascular complications associated with device</b>		
Vascular stent thrombosis	1	0
<b>Withdrawal and rebound effects</b>		
Drug withdrawal syndrome	5	0
Withdrawal syndrome	23	0
<b>General disorders SOC TOTAL</b>	<b>70396</b>	<b>164</b>

## Case Series Drug Analysis Print

### Name: COVID-19 mRNA Pfizer- BioNTech Vaccine Analysis Print

Report Run Date: 29-Jul-2021  
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 28-Jul-2021 18:30:14  
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i><b>Bile duct infections and inflammations</b></i>		
Biliary colic	7	0
Cholangitis	1	0
<i><b>Cholecystitis and cholelithiasis</b></i>		
Cholecystitis	1	0
Cholecystitis acute	2	0
Cholelithiasis	6	0
<i><b>Cholestasis and jaundice</b></i>		
Cholestasis	2	0
Jaundice	14	0
Jaundice cholestatic	6	0
<i><b>Gallbladder disorders NEC</b></i>		
Gallbladder disorder	1	0
<i><b>Hepatic and hepatobiliary disorders NEC</b></i>		
Liver disorder	9	0
<i><b>Hepatic enzymes and function abnormalities</b></i>		
Hepatic function abnormal	2	0
<i><b>Hepatic failure and associated disorders</b></i>		
Acute hepatic failure	1	0
Hepatic failure	2	1
<i><b>Hepatic fibrosis and cirrhosis</b></i>		
Hepatic cirrhosis	1	0
<i><b>Hepatic vascular disorders</b></i>		
Congestive hepatopathy	2	0
Hepatic artery embolism	1	0
Hepatic haemorrhage	2	0
Hepatic vein thrombosis	5	0
Portal vein thrombosis	4	0
<i><b>Hepatobiliary signs and symptoms</b></i>		
Hepatic pain	18	0
Hepatomegaly	1	0
Liver tenderness	3	0
<i><b>Hepatocellular damage and hepatitis NEC</b></i>		
Autoimmune hepatitis	5	0
Drug-induced liver injury	2	0
Hepatitis	9	0
Immune-mediated hepatic disorder	1	0
Liver injury	8	0
<b>Hepatic disorders SOC TOTAL</b>	<b>116</b>	<b>1</b>

## Case Series Drug Analysis Print

### Name: COVID-19 mRNA Pfizer- BioNTech Vaccine Analysis Print

Report Run Date: 29-Jul-2021  
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 28-Jul-2021 18:30:14  
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	10	0
<i>Allergic conditions NEC</i>		
Allergic oedema	11	0
Allergy to animal	1	0
Allergy to arthropod bite	5	0
Allergy to arthropod sting	1	0
Allergy to metals	1	0
Allergy to sting	1	0
Hypersensitivity	683	0
Infusion related hypersensitivity reaction	1	0
Mite allergy	1	0
Multiple allergies	6	0
Serum sickness	2	0
Serum sickness-like reaction	3	0
Type I hypersensitivity	1	0
Type III immune complex mediated reaction	1	0
Type IV hypersensitivity reaction	6	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergic reaction to excipient	4	0
Allergy to chemicals	2	0
Allergy to vaccine	29	0
Contrast media reaction	1	0
Drug hypersensitivity	19	0
Food allergy	15	0
Oral allergy syndrome	2	0
Reaction to colouring	1	0
Reaction to excipient	8	0
Reaction to preservatives	4	0
Rubber sensitivity	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	386	2
Anaphylactic shock	35	0
Anaphylactoid reaction	19	0
Anaphylactoid shock	4	0
<i>Atopic disorders</i>		
Atopy	1	0
Seasonal allergy	81	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	28	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	34	0
Graft versus host disease	1	0
Immune system disorder	16	0
Immune-mediated adverse reaction	5	0
Immunisation reaction	1	0
Sensitisation	4	0
Systemic immune activation	2	0
<i>Immunodeficiency disorders NEC</i>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	1	0
Immunosuppression	1	0
<i>Transplant rejections</i>		

## Case Series Drug Analysis Print

### Name: COVID-19 mRNA Pfizer- BioNTech Vaccine Analysis Print

Report Run Date: 29-Jul-2021

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
Immune system disorders cont'd		
Corneal graft rejection	5	0
Kidney transplant rejection	1	0
Solid organ transplant rejection	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>1447</b>	<b>2</b>

## Case Series Drug Analysis Print

### Name: COVID-19 mRNA Pfizer- BioNTech Vaccine Analysis Print

Report Run Date: 29-Jul-2021  
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 28-Jul-2021 18:30:14  
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Infections</b>		
<b><i>Abdominal and gastrointestinal infections</i></b>		
Abdominal abscess	1	0
Abdominal infection	1	0
Anal abscess	3	0
Appendicitis	23	0
Appendicitis perforated	2	0
Diverticulitis	7	0
Dysentery	1	0
Gastric infection	2	0
Gastroenteritis	21	0
Mesenteric abscess	1	0
Peritonitis	1	1
Rectal abscess	1	0
<b><i>Adenoviral infections</i></b>		
Adenoviral conjunctivitis	1	0
<b><i>Aspergillus infections</i></b>		
Bronchopulmonary aspergillosis	1	0
<b><i>Bacterial infections NEC</i></b>		
Abscess bacterial	1	0
Arthritis bacterial	3	0
Bacterial colitis	1	0
Bacterial diarrhoea	1	0
Bacterial infection	9	0
Cellulitis	132	0
Conjunctivitis bacterial	1	0
Ear infection bacterial	1	0
Folliculitis	12	0
Gangrene	1	0
Injection site cellulitis	2	0
Meningitis bacterial	3	0
Paronychia	2	0
Perichondritis	1	0
Periorbital cellulitis	1	0
Sinusitis bacterial	1	0
Skin bacterial infection	2	0
Tonsillitis bacterial	3	0
Urinary tract infection bacterial	1	0
Vaccination site cellulitis	15	0
Zoonotic bacterial infection	1	1
<b><i>Bartonella infections</i></b>		
Cat scratch disease	1	0
<b><i>Bone and joint infections</i></b>		
Abscess jaw	1	0
Arthritis infective	1	0
Osteomyelitis	1	0
<b><i>Borrelial infections</i></b>		
Lyme disease	1	0
Relapsing fever	1	0
<b><i>Breast infections</i></b>		
Breast abscess	2	0
Mastitis	50	0
<b><i>Caliciviral infections</i></b>		
Gastroenteritis norovirus	1	0

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Infections</b>		
<i>Infections cont'd</i>		
<b><i>Campylobacter infections</i></b>		
Campylobacter gastroenteritis	1	0
Campylobacter infection	1	0
<b><i>Candida infections</i></b>		
Anal candidiasis	3	0
Balanitis candida	1	0
Candida infection	40	0
Oral candidiasis	34	0
Skin candida	1	0
Systemic candida	1	0
Vulvovaginal candidiasis	35	0
<b><i>Cardiac infections</i></b>		
Pericarditis infective	1	0
<b><i>Central nervous system and spinal infections</i></b>		
CNS ventriculitis	1	0
Cavernous sinus thrombosis	1	0
Encephalitis	14	0
Meningitis	4	0
Meningitis aseptic	1	0
Myelitis	4	0
<b><i>Clostridia infections</i></b>		
Clostridium difficile infection	2	0
<b><i>Coronavirus infections</i></b>		
Asymptomatic COVID-19	11	0
COVID-19	844	34
COVID-19 pneumonia	34	13
Coronavirus infection	6	0
Post-acute COVID-19 syndrome	1	0
Severe acute respiratory syndrome	1	0
Suspected COVID-19	44	1
<b><i>Coxiella infections</i></b>		
Q fever	9	0
<b><i>Cytomegaloviral infections</i></b>		
Cytomegalovirus infection	2	0
Cytomegalovirus syndrome	1	0
<b><i>Dental and oral soft tissue infections</i></b>		
Abscess oral	4	0
Gingivitis	7	0
Parotitis	9	0
Pulpitis dental	1	0
Sialoadenitis	3	0
Tooth abscess	8	0
Tooth infection	8	0
<b><i>Ear infections</i></b>		
Ear infection	59	0
Labyrinthitis	71	0
Mastoiditis	1	0
Otitis media	4	0
Otitis media acute	1	0
<b><i>Ectoparasitic infestations</i></b>		
Acarodermatitis	4	0
Bed bug infestation	1	0
<b><i>Epstein-Barr viral infections</i></b>		



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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Infections</b> Infections cont'd		
Epstein-Barr virus infection	3	0
Infectious mononucleosis	21	0
<b>Eye and eyelid infections</b>		
Conjunctivitis	53	0
Eye abscess	1	0
Eye infection	15	0
Eyelid infection	2	0
Hordeolum	20	0
Periorbital infection	2	0
<b>Female reproductive tract infections</b>		
Bartholinitis	1	0
Endometritis	3	0
Funisitis	1	0
Pelvic inflammatory disease	1	0
Vaginal infection	1	0
Vulval abscess	1	0
Vulvitis	1	0
<b>Fungal infections NEC</b>		
Fungal infection	8	0
Fungal skin infection	4	0
Onychomycosis	1	0
Oral fungal infection	1	0
Pneumonia fungal	2	0
Vulvovaginal mycotic infection	6	0
<b>Hepatitis virus infections</b>		
Hepatitis A	1	0
Hepatitis E	1	0
<b>Hepatobiliary and spleen infections</b>		
Biliary sepsis	1	0
Cholecystitis infective	1	0
<b>Herpes viral infections</b>		
Disseminated varicella zoster virus infection	1	0
Eczema herpeticum	2	0
Genital herpes	66	0
Genital herpes simplex	5	0
Herpes ophthalmic	3	0
Herpes simplex	22	0
Herpes simplex encephalitis	1	1
Herpes simplex reactivation	2	0
Herpes virus infection	9	0
Herpes zoster	1114	0
Herpes zoster meningoencephalitis	1	0
Herpes zoster oticus	11	0
Herpes zoster reactivation	1	0
Nasal herpes	3	0
Ophthalmic herpes zoster	3	0
Oral herpes	240	0
Varicella	20	0
Varicella zoster virus infection	1	0
<b>Infections NEC</b>		
Abscess	28	0
Abscess limb	5	0
Abscess soft tissue	1	0

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
Genital abscess	1	0
Infected bite	3	0
Infected cyst	2	0
Infection	173	0
Injection site abscess	1	0
Injection site infection	5	0
Localised infection	20	0
Lymph gland infection	7	0
Lymph node abscess	4	0
Opportunistic infection	1	0
Respiratory tract infection	6	0
Vaccination site abscess	6	0
Vaccination site infection	13	0
Vaccine breakthrough infection	23	0
Vestibulitis	2	0
Wound infection	1	0
<b>Infectious transmissions</b>		
Secondary transmission	9	0
<b>Influenza viral infections</b>		
Influenza	1089	0
<b>Klebsiella infections</b>		
Klebsiella infection	1	0
<b>Lower respiratory tract and lung infections</b>		
Bronchitis	16	0
Infectious pleural effusion	1	0
Lower respiratory tract infection	147	7
Pneumonia	86	10
Sputum purulent	1	0
<b>Male reproductive tract infections</b>		
Epididymitis	3	0
Orchitis	3	0
Prostate infection	1	0
<b>Mumps viral infections</b>		
Mumps	7	0
<b>Muscle and soft tissue infections</b>		
Abscess neck	1	0
Infective tenosynovitis	1	0
Necrotising fasciitis	2	0
Soft tissue infection	1	0
<b>Neisseria infections</b>		
Gonorrhoea	1	0
<b>Plasmodia infections</b>		
Malaria	1	1
<b>Pneumocystis infections</b>		
Pneumocystis jirovecii pneumonia	1	0
<b>Prion-associated disorders</b>		
Creutzfeldt-Jakob disease	1	0
<b>Retroviral infections</b>		
HIV infection	1	0
<b>Rotaviral infections</b>		
Gastroenteritis rotavirus	1	0
<b>Rubeola viral infections</b>		
Measles	4	0

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Infections</b>		
<i>Infections cont'd</i>		
<b><i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i></b>		
Bacteraemia	1	0
Neutropenic sepsis	3	1
Sepsis	35	5
Sepsis syndrome	1	0
Septic rash	1	0
Septic shock	4	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	2	0
Impetigo	7	0
Infected skin ulcer	1	0
Injection site pustule	1	0
Nail infection	1	0
Pustule	9	0
Rash pustular	9	0
Skin infection	26	0
Subcutaneous abscess	6	0
Vaccination site pustule	4	0
<b><i>Staphylococcal infections</i></b>		
Furuncle	30	0
Pneumonia staphylococcal	1	0
Staphylococcal abscess	1	0
Staphylococcal infection	3	0
Staphylococcal sepsis	1	0
<b><i>Streptococcal infections</i></b>		
Meningitis pneumococcal	1	0
Pharyngitis streptococcal	5	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	1	0
Tinea infection	1	0
Tinea pedis	1	0
Tinea versicolour	1	0
<b><i>Treponema infections</i></b>		
Syphilis	1	0
<b><i>Trypanosomal infections</i></b>		
African trypanosomiasis	2	0
<b><i>Tuberculous infections</i></b>		
Lymph node tuberculosis	1	0
Pulmonary tuberculosis	1	0
Tuberculosis	1	0
<b><i>Upper respiratory tract infections</i></b>		
Acute sinusitis	4	0
Croup infectious	1	0
Epiglottitis	1	0
Laryngitis	20	0

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
Nasopharyngitis	660	0
Peritonsillar abscess	2	0
Pharyngitis	21	0
Rhinitis	34	0
Sinusitis	111	0
Tonsillitis	74	0
Tracheitis	4	0
Tracheostomy infection	1	0
Upper respiratory tract infection	6	0
<b>Urinary tract infections</b>		
Cystitis	56	0
Kidney infection	28	0
Pyelonephritis	1	0
Urinary tract infection	123	0
<b>Vascular infections</b>		
Haematoma infection	1	0
Infected lymphocele	1	0
Infusion site infection	1	0
Lymphangitis	7	0
<b>Viral infections NEC</b>		
Arthritis viral	1	0
Conjunctivitis viral	2	0
Encephalitis viral	3	0
Eye infection viral	2	0
Gastroenteritis viral	19	0
Hepatitis viral	2	0
Meningitis viral	7	0
Oral viral infection	1	0
Pleurisy viral	1	0
Pneumonia viral	2	1
Post viral fatigue syndrome	34	0
Sweating fever	69	0
Vestibular neuronitis	20	0
Viral diarrhoea	2	0
Viral infection	38	0
Viral labyrinthitis	3	0
Viral pericarditis	2	0
Viral pharyngitis	13	0
Viral rash	40	0
Viral sinusitis	1	0
Viral tonsillitis	1	0
<b>Infections SOC TOTAL</b>	<b>6531</b>	<b>77</b>

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Injuries</b>		
<b><i>Abdominal and gastrointestinal injuries NEC</i></b>		
Mouth injury	3	0
Oral contusion	3	0
Palate injury	1	0
Rectal injury	1	0
Splenic rupture	6	0
Tongue injury	1	0
Tooth fracture	1	0
Tooth injury	1	0
<b><i>Accidental exposures to product</i></b>		
Accidental exposure to product	15	0
<b><i>Anaesthetic and allied procedural complications</i></b>		
Airway complication of anaesthesia	1	0
Delayed recovery from anaesthesia	2	0
Sedation complication	1	0
<b><i>Atmospheric pressure injuries</i></b>		
Barotitis media	1	0
Hypobarism	1	0
<b><i>Bone and joint injuries NEC</i></b>		
Joint injury	6	0
<b><i>Cardiovascular injuries</i></b>		
Heart injury	4	0
Vascular injury	5	0
<b><i>Cerebral injuries NEC</i></b>		
Brain contusion	1	0
Brain herniation	1	0
Concussion	2	0
Craniocerebral injury	1	0
Subarachnoid haematoma	1	0
Subdural haematoma	5	0
Subdural haemorrhage	5	0
Traumatic intracranial haemorrhage	1	1
<b><i>Chemical injuries</i></b>		
Chemical cystitis	1	0
<b><i>Chest and respiratory tract injuries NEC</i></b>		
Chest crushing	8	0
Foreign body in throat	1	0
<b><i>Conditions caused by cold</i></b>		
Chillblains	49	0
<b><i>Cranial nerve injuries</i></b>		
Vth nerve injury	1	0
<b><i>Ear injuries NEC</i></b>		
Ear injury	1	0
<b><i>Exposures associated with pregnancy, delivery and lactation</i></b>		
Exposure during pregnancy	7	0
Exposure via breast milk	34	0
Foetal exposure during pregnancy	23	0
Maternal exposure before pregnancy	2	0
Maternal exposure during breast feeding	1028	0
Maternal exposure during pregnancy	488	0
Maternal exposure timing unspecified	1	0
Paternal exposure before pregnancy	2	0
<b><i>Exposures to agents or circumstances NEC</i></b>		

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Injuries</b> Injuries cont'd		
Exposure to SARS-CoV-2	2	0
Exposure to vaccinated person	3	0
<b>Eye and ear procedural complications</b>		
Toxic anterior segment syndrome	1	0
<b>Eye injuries NEC</b>		
Eye contusion	13	0
Eye injury	13	0
Foreign body in eye	2	0
Injury corneal	1	0
Periorbital haematoma	1	0
Retinal injury	2	0
Superficial injury of eye	1	0
<b>Foetal and neonatal conditions associated with product exposure</b>		
Intoxication by breast feeding	1	0
<b>Fractures and dislocations NEC</b>		
Bone fragmentation	1	0
Fracture	1	0
Joint dislocation	2	0
Multiple fractures	1	0
<b>Gastrointestinal and hepatobiliary procedural complications</b>		
Post procedural constipation	1	0
Postoperative ileus	1	0
Procedural nausea	6	0
Procedural vomiting	1	0
<b>Heat injuries (excl thermal burns)</b>		
Heat cramps	2	0
Heat exhaustion	2	0
Heat illness	1	0
Heat oedema	7	0
Heat stroke	3	0
<b>Intentional product use issues</b>		
Intentional product use issue	1	0
<b>Limb fractures and dislocations</b>		
Atypical femur fracture	1	0
Clavicle fracture	20	0
Femoral neck fracture	1	0
Hip 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	1	0
Dose calculation error	1	0
Inadequate aseptic technique in use of product	1	0
Medication error	18	0
Prescription drug used without a prescription	2	0
Product use complaint	1	0
Product use issue	13	0
Vaccination error	6	0
Wrong dose	3	0
Wrong drug	11	0
Wrong technique in product usage process	3	0
<b>Muscle, tendon and ligament injuries</b>		
Epicondylitis	12	0

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Injuries</b> Injuries cont'd		
Ligament sprain	7	0
Mallet finger	1	0
Muscle injury	13	0
Muscle rupture	4	0
Muscle strain	22	0
Post-traumatic neck syndrome	1	0
Tendon injury	5	0
Tendon rupture	8	0
<b>Musculoskeletal procedural complications</b>		
Periprosthetic osteolysis	1	0
Post laminectomy syndrome	1	0
<b>Nerve injuries NEC</b>		
Nerve injury	53	0
<b>Neurological and psychiatric procedural complications</b>		
Post procedural stroke	1	0
Procedural dizziness	11	0
<b>Non-occupational environmental exposures</b>		
Exposure to extreme temperature	1	0
<b>Non-site specific injuries NEC</b>		
Arthropod bite	2	0
Arthropod sting	3	0
Bite	1	0
Electric shock	11	0
Fall	115	1
Foreign body	2	0
Injury	5	0
Nervous system injury	1	0
Post concussion syndrome	1	0
Traumatic haematoma	1	0
Wound	5	0
Wound complication	8	0
Wound haematoma	1	0
Wound haemorrhage	2	0
Wound secretion	3	0
<b>Non-site specific procedural complications</b>		
Incision site pain	2	0
Infusion related reaction	6	0
Injection related reaction	37	0
Post procedural complication	3	0
Procedural pain	2	0
Seroma	1	0
<b>Occupational exposures</b>		
Occupational exposure to SARS-CoV-2	1	0
Occupational exposure to product	1	0
<b>Off label uses</b>		
Off label use	45	0
<b>Overdoses NEC</b>		
Overdose	27	0
<b>Pathways and sources of exposure</b>		
Exposure via unknown route	1	0
<b>Pelvic fractures and dislocations</b>		
Pelvic fracture	1	0
<b>Peripheral nerve injuries</b>		

## Case Series Drug Analysis Print

### Name: COVID-19 mRNA Pfizer- BioNTech Vaccine Analysis Print

Report Run Date: 29-Jul-2021  
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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Injuries</b> Injuries cont'd		
Brachial plexus injury	1	0
Ulnar nerve injury	4	0
<b>Poisoning and toxicity</b>		
Alcohol poisoning	1	0
Poisoning	9	0
Toxicity to various agents	2	0
<b>Product administration errors and issues</b>		
Accidental overdose	4	0
Contraindicated product administered	1	0
Expired product administered	10	0
Inappropriate schedule of product administration	275	0
Incomplete course of vaccination	1	0
Incorrect dose administered	51	0
Incorrect drug administration rate	1	0
Incorrect product formulation administered	2	0
Incorrect route of product administration	4	0
Poor quality product administered	2	0
Product administered at inappropriate site	11	0
Product administered to patient of inappropriate age	1	0
Product administration error	5	0
Product dose omission issue	3	0
Wrong product administered	18	0
<b>Product confusion errors and issues</b>		
Product label confusion	1	0
<b>Product dispensing errors and issues</b>		
Product dispensing error	3	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	1	0
Product preparation issue	5	0
<b>Product prescribing errors and issues</b>		
Contraindicated product prescribed	2	0
Product prescribing error	1	0
<b>Product selection errors and issues</b>		
Product selection error	2	0
<b>Radiation injuries</b>		
Sunburn	17	0
<b>Renal and urinary tract injuries NEC</b>		
Foreign body in urogenital tract	1	0
<b>Site specific injuries NEC</b>		
Face crushing	1	0
Head injury	30	0
Limb crushing injury	2	0
Limb injury	68	0
Nasal injury	2	0
Neck crushing	1	0
Neck injury	1	0
<b>Skin injuries NEC</b>		
Contusion	802	0
Nail avulsion	1	0
Scar	12	0
Scratch	7	0



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Reaction Name	Total	Fatal
<b>Injuries</b> Injuries cont'd		
Skin abrasion	5	0
Skin injury	3	0
Skin laceration	3	0
Skin wound	2	0
Subcutaneous haematoma	2	0
<b>Skin procedural complications</b>		
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 fractures and dislocations</b>		
Spinal fracture	3	0
<b>Stoma complications</b>		
Gastrointestinal stoma complication	1	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	2	0
Burn of internal organs	2	0
Burn oral cavity	2	0
Burns second degree	4	0
Thermal burn	16	0
Thermal burns of eye	9	0
<b>Underdoses NEC</b>		
Underdose	6	0
<b>Vaccination related complications</b>		
Adverse event following immunisation	2	0
Vaccination complication	41	0
<b>Injuries SOC TOTAL</b>	<b>3777</b>	<b>2</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<b><i>Adrenal cortex tests</i></b>		
Cortisol decreased	3	0
<b><i>Adrenal medulla tests</i></b>		
Epinephrine increased	1	0
<b><i>Auditory and vestibular diagnostic procedures</i></b>		
Acoustic stimulation tests	5	0
Audiogram abnormal	1	0
<b><i>Autoimmunity analyses</i></b>		
Antinuclear antibody	1	0
Antinuclear antibody increased	1	0
Rheumatoid factor	3	0
<b><i>Blood counts NEC</i></b>		
Blood count	4	0
Blood count abnormal	2	0
<b><i>Blood gas and acid base analyses</i></b>		
Acid base balance abnormal	1	0
Blood lactic acid	2	0
Blood lactic acid decreased	1	0
Blood lactic acid increased	4	0
Blood pH	6	0
Blood pH increased	6	0
Oxygen consumption decreased	2	0
Oxygen saturation	7	0
Oxygen saturation decreased	49	0
PO2 decreased	1	0
<b><i>Bone marrow and immune tissue histopathology procedures</i></b>		
Aspiration bone marrow	1	0
Biopsy lymph gland	1	0
<b><i>Bone marrow and immune tissue imaging procedures</i></b>		
Lymph nodes scan abnormal	1	0
Scan lymph nodes	4	0
<b><i>Carbohydrate tolerance analyses (incl diabetes)</i></b>		
Blood glucose	6	0
Blood glucose abnormal	9	0
Blood glucose decreased	26	0
Blood glucose fluctuation	14	0
Blood glucose increased	83	0
Blood glucose normal	1	0
Glycosylated haemoglobin increased	1	0
<b><i>Cardiac auscultatory investigations</i></b>		
Cardiac murmur	18	0
Heart sounds	2	0
Heart sounds abnormal	3	0
<b><i>Cardiac function diagnostic procedures</i></b>		
Cardiac monitoring	1	0
Cardiac output	1	0
Central venous pressure	1	0
Echocardiogram	1	0
Stroke volume decreased	1	0
<b><i>Cardiac imaging procedures</i></b>		
Magnetic resonance imaging heart	1	0
Scan myocardial perfusion abnormal	1	0
<b><i>Cell marker analyses</i></b>		

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Reaction Name	Total	Fatal
<b>Investigations</b>		
Investigations cont'd		
Prostatic specific antigen increased	2	0
<b>Central nervous system imaging procedures</b>		
Computerised tomogram head	4	0
Magnetic resonance imaging head	11	0
Magnetic resonance imaging head abnormal	1	0
<b>Cerebrospinal fluid tests (excl microbiology)</b>		
CSF pressure	1	0
<b>Chemistry analyses NEC</b>		
Histamine level increased	1	0
Inflammatory marker increased	3	0
Renin	1	0
<b>Cholesterol analyses</b>		
Blood cholesterol increased	5	0
Remnant-like lipoprotein particles	3	0
<b>Coagulation and bleeding analyses</b>		
Activated partial thromboplastin time prolonged	15	0
Activated partial thromboplastin time shortened	1	0
Bleeding time	1	0
Bleeding time abnormal	1	0
Bleeding time prolonged	4	0
Blood thromboplastin	1	0
Clot retraction	1	1
Coagulation factor VIII level decreased	1	0
Coagulation time prolonged	9	0
Coagulation time shortened	1	0
Fibrin D dimer increased	6	0
International normalised ratio abnormal	5	0
International normalised ratio decreased	18	0
International normalised ratio fluctuation	1	0
International normalised ratio increased	47	0
<b>Digestive enzymes</b>		
Amylase increased	1	0
<b>ECG investigations</b>		
Electrocardiogram	2	0
Electrocardiogram QRS complex prolonged	1	0
Electrocardiogram QT prolonged	2	0
Electrocardiogram ST segment elevation	4	0
Electrocardiogram ST-T segment abnormal	1	0
Electrocardiogram T wave inversion	3	0
Electrocardiogram abnormal	12	0
Electrocardiogram normal	2	0
Electrocardiogram repolarisation abnormality	1	0
QRS axis abnormal	1	0
<b>Endocrine analyses and imaging NEC</b>		
Hormone level abnormal	29	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
<b>Foetal and neonatal diagnostic procedures</b>		
Foetal heart rate abnormal	2	2

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Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Foetal heart rate increased	1	0
Foetal non-stress test	1	0
<b>Gastrointestinal and abdominal imaging procedures</b>		
Computerised tomogram abdomen	1	0
Sigmoidoscopy abnormal	1	0
<b>Gastrointestinal function diagnostic procedures</b>		
Gastric pH decreased	1	0
<b>Gastrointestinal, pancreatic and APUD hormone analyses</b>		
Blood insulin	1	0
Blood insulin decreased	1	0
<b>Haematological analyses NEC</b>		
Blood viscosity abnormal	1	0
Plasma viscosity	1	0
Red blood cell sedimentation rate increased	5	0
<b>Heart rate and pulse investigations</b>		
Carotid pulse	1	0
Heart rate	288	0
Heart rate abnormal	42	0
Heart rate decreased	45	0
Heart rate increased	568	0
Heart rate irregular	111	0
Maximum heart rate	1	0
Pulse abnormal	13	0
Pulse pressure increased	1	0
Radial pulse abnormal	1	0
Sinus rhythm	4	0
<b>Imaging procedures NEC</b>		
Computerised tomogram	3	0
Magnetic resonance imaging	2	0
Magnetic resonance imaging abnormal	1	0
Scan	1	0
<b>Immunoglobulin analyses</b>		
Blood immunoglobulin G increased	1	0
Blood immunoglobulin M	1	0
Blood immunoglobulin M increased	1	0
<b>Immunology analyses NEC</b>		
Antibody test	4	0
Immunology test	8	0
<b>Immunology skin tests NEC</b>		
Skin test positive	1	0
<b>Investigations NEC</b>		
Blood test	14	0
Blood test abnormal	30	0
False positive investigation result	1	0
Laboratory test	1	0
Polymerase chain reaction positive	33	0
Quality of life decreased	1	0
Systemic lupus erythematosus disease activity index increased	1	0
<b>Liver function analyses</b>		
Alanine aminotransferase increased	19	0
Aspartate aminotransferase	1	0
Aspartate aminotransferase increased	2	0
Blood bilirubin increased	3	0

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Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Gamma-glutamyltransferase increased	4	0
Hepatic enzyme increased	4	0
Liver function test	1	0
Liver function test abnormal	20	0
Liver function test increased	14	0
Transaminases increased	2	0
<b>Metabolism tests NEC</b>		
Blood ketone body	3	0
Blood ketone body increased	1	0
Blood uric acid increased	2	0
Brain natriuretic peptide increased	1	0
Ubiquinone	1	0
Urine ketone body present	1	0
<b>Microbiology and serology tests NEC</b>		
Culture negative	1	0
<b>Mineral and electrolyte analyses</b>		
Blood copper increased	1	0
Blood iron	1	0
Blood iron decreased	5	0
Blood magnesium decreased	1	0
Blood phosphorus decreased	1	0
Blood phosphorus increased	1	0
Blood potassium abnormal	1	0
Blood potassium decreased	4	0
Blood potassium increased	2	0
Blood sodium decreased	8	0
Serum ferritin	1	0
Serum ferritin decreased	3	0
Serum ferritin increased	1	0
<b>Musculoskeletal and soft tissue imaging procedures</b>		
Skull X-ray	6	0
<b>Musculoskeletal and soft tissue tests NEC</b>		
Swollen joint count increased	1	0
<b>Mycobacteria identification and serology</b>		
Tuberculin test positive	1	0
<b>Neurologic diagnostic procedures</b>		
Coma scale abnormal	3	0
Hoover's sign of leg paresis	1	0
Lumbar puncture	3	0
Temperature perception test increased	1	0
<b>Ophthalmic function diagnostic procedures</b>		
Corneal reflex decreased	1	0
Intraocular pressure increased	7	0
Intraocular pressure test	1	0
<b>Physical examination procedures and organ system status</b>		
Body temperature	191	0
Body temperature abnormal	31	0
Body temperature decreased	31	0
Body temperature fluctuation	26	0
Body temperature increased	310	0
Body temperature normal	1	0
Breath sounds abnormal	1	0
General physical condition abnormal	1	0

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Reaction Name	Total	Fatal
<b>Investigations</b>		
Investigations cont'd		
Grip strength	2	0
Grip strength decreased	14	0
Head lag	5	0
Lymph node palpable	31	0
Menstruation normal	3	0
Muscle strength abnormal	1	0
Ophthalmological examination	2	0
Palpatory finding abnormal	1	0
Product residue present	2	0
Psoriasis area severity index decreased	1	0
Respiratory rate	7	0
Respiratory rate decreased	12	0
Respiratory rate increased	28	0
Skin temperature	28	0
Temperature difference of extremities	7	0
Weight	1	0
Weight decreased	67	0
Weight increased	19	0
<b><i>Pituitary analyses anterior</i></b>		
Blood corticotrophin	1	0
Blood follicle stimulating hormone	1	0
Blood growth hormone	3	0
Blood prolactin	2	0
Blood prolactin increased	1	0
Blood thyroid stimulating hormone decreased	1	0
Blood thyroid stimulating hormone increased	3	0
<b><i>Platelet analyses</i></b>		
Mean platelet volume decreased	1	0
Mean platelet volume increased	1	0
Platelet count	2	0
Platelet count decreased	55	0
Platelet count increased	1	0
<b><i>Protein analyses NEC</i></b>		
Alpha 1 globulin decreased	1	0
Alpha 2 globulin decreased	1	0
C-reactive protein increased	14	0
<b><i>Red blood cell analyses</i></b>		
Haematocrit	1	0
Haemoglobin decreased	10	0
<b><i>Renal function analyses</i></b>		
Blood creatinine increased	1	0
Glomerular filtration rate decreased	2	0
<b><i>Reproductive hormone analyses</i></b>		
Anti-Muellerian hormone level decreased	1	0
False negative pregnancy test	6	0
Female sex hormone level	2	0
Pregnancy test	16	0
Pregnancy test false positive	1	0
Pregnancy test positive	1	0
<b><i>Reproductive organ and breast histopathology procedures</i></b>		
Smear cervix	1	0
<b><i>Reproductive organ and breast imaging procedures</i></b>		
Hysteroscopy	2	0

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Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
<b><i>Respiratory and pulmonary function diagnostic procedures</i></b>		
Forced expiratory volume increased	2	0
Maximal voluntary ventilation	1	0
Peak expiratory flow rate	1	0
Peak expiratory flow rate decreased	4	0
Pulmonary function test	2	0
Total lung capacity decreased	1	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	18	0
Chest X-ray abnormal	1	0
Chest X-ray normal	1	0
Chest scan	1	0
Computerised tomogram thorax	1	0
<b><i>Skeletal and cardiac muscle analyses</i></b>		
Blood creatine phosphokinase increased	4	0
Myocardial necrosis marker	1	0
Troponin increased	7	0
<b><i>Therapeutic drug monitoring analyses</i></b>		
Analgesic drug level	4	0
Anticoagulation drug level above therapeutic	1	0
Anticoagulation drug level below therapeutic	5	0
Anticoagulation drug level increased	1	0
Drug level decreased	1	0
<b><i>Thyroid analyses</i></b>		
Anti-thyroid antibody	1	0
Thyroid function test abnormal	3	0
Thyroxine free increased	2	0
Tri-iodothyronine	1	0
Tri-iodothyronine decreased	3	0
<b><i>Tissue enzyme analyses NEC</i></b>		
Blood alkaline phosphatase increased	2	0
<b><i>Toxicology laboratory analyses</i></b>		
Blood caffeine decreased	1	0
Drug screen positive	2	0
Opiates	1	0
<b><i>Urinalysis NEC</i></b>		
Blood urine	10	0
Blood urine present	35	0
Cells in urine	1	0
Glucose urine present	1	0
Urine analysis abnormal	4	0
pH urine	5	0
pH urine increased	2	0
<b><i>Urinary tract function analyses NEC</i></b>		
Urine output	10	0
Urine output decreased	7	0
Urine output increased	5	0
<b><i>Urinary tract imaging procedures</i></b>		
Cystoscopy	2	0
<b><i>Vascular imaging procedures NEC</i></b>		

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Reaction Name	Total	Fatal
<b>Investigations</b>		
Investigations cont'd		
Venogram	1	0
<b>Vascular tests NEC (incl blood pressure)</b>		
Blood pressure abnormal	6	0
Blood pressure decreased	49	0
Blood pressure diastolic	1	0
Blood pressure diastolic decreased	1	0
Blood pressure diastolic increased	2	0
Blood pressure increased	171	0
Blood pressure measurement	29	0
Blood pressure normal	1	0
Blood pressure systolic	1	0
Blood pressure systolic decreased	3	0
Blood pressure systolic increased	1	0
<b>Virus identification and serology</b>		
Coronavirus test	11	0
Coronavirus test positive	3	0
HIV test	1	0
SARS-CoV-1 test positive	1	0
SARS-CoV-2 antibody test	9	0
SARS-CoV-2 antibody test negative	12	0
SARS-CoV-2 antibody test positive	2	0
SARS-CoV-2 test	24	0
SARS-CoV-2 test false negative	1	0
SARS-CoV-2 test false positive	2	0
SARS-CoV-2 test negative	7	0
SARS-CoV-2 test positive	89	0
Viral test	4	0
<b>Vitamin analyses</b>		
Blood folate decreased	3	0
Vitamin B12	1	0
Vitamin B12 abnormal	1	0
Vitamin B12 decreased	1	0
Vitamin D	2	0
Vitamin D decreased	3	0
<b>Water and electrolyte analyses NEC</b>		
Urine osmolarity	1	0
Volume blood	1	0
<b>White blood cell analyses</b>		
Eosinophil count increased	1	0
Lymphocyte count	1	0
Lymphocyte count decreased	1	0
Neutrophil count	1	0
Neutrophil count decreased	4	0
White blood cell count	3	0
White blood cell count decreased	9	0
White blood cell count increased	6	0
<b>Investigations SOC TOTAL</b>	<b>3403</b>	<b>3</b>



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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Appetite disorder	11	0
Decreased appetite	868	0
Diet refusal	1	0
Eating disorder symptom	2	0
Food craving	8	0
Food refusal	8	0
Hyperphagia	7	0
Hypophagia	13	0
Increased appetite	21	0
Salt craving	2	0
<i><b>Calcium metabolism disorders</b></i>		
Hypocalcaemia	3	0
Tetany	3	0
<i><b>Diabetes mellitus (incl subtypes)</b></i>		
Diabetes mellitus	34	0
Diabetes mellitus inadequate control	11	1
Increased insulin requirement	1	0
Insulin resistant diabetes	1	0
Latent autoimmune diabetes in adults	2	0
Type 1 diabetes mellitus	14	0
Type 2 diabetes mellitus	3	0
<i><b>Diabetic complications NEC</b></i>		
Diabetic complication	2	0
Diabetic ketoacidosis	11	0
Diabetic ketosis	1	0
<i><b>Disorders of purine metabolism</b></i>		
Gout	73	0
<i><b>Electrolyte imbalance NEC</b></i>		
Fluid imbalance	1	0
<i><b>Fat soluble vitamin deficiencies and disorders</b></i>		
Vitamin D deficiency	1	0
<i><b>Fluid intake increased</b></i>		
Polydipsia	5	0
<i><b>Food malabsorption and intolerance syndromes (excl sugar intolerance)</b></i>		
Alcohol intolerance	2	0
Dairy intolerance	1	0
Food intolerance	8	0
Gluten sensitivity	5	0
Histamine intolerance	3	0
<i><b>General nutritional disorders NEC</b></i>		
Abnormal loss of weight	10	0
Abnormal weight gain	10	0
Cachexia	1	0
Feeding disorder	48	0
Food aversion	7	0
Malnutrition	1	0
Neonatal insufficient breast milk syndrome	4	0
Overweight	1	0
Poor feeding infant	9	0
Weight loss poor	2	0
<i><b>Hyperglycaemic conditions NEC</b></i>		
Hyperglycaemia	58	0

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b> Metabolic disorders cont'd		
Insulin resistance	4	0
<b>Hypoglycaemic conditions NEC</b>		
Glycopenia	1	0
Hypoglycaemia	69	0
Hypoglycaemia unawareness	2	0
Postprandial hypoglycaemia	1	0
<b>Iron deficiencies</b>		
Iron deficiency	10	0
<b>Iron excess</b>		
Haemochromatosis	1	0
Iron overload	1	0
<b>Lipid metabolism and deposit disorders NEC</b>		
Body fat disorder	1	0
<b>Metabolic acidoses (excl diabetic acidoses)</b>		
Ketoacidosis	4	0
Lactic acidosis	1	0
Metabolic acidosis	2	0
<b>Mixed acid-base disorders</b>		
Acidosis	3	0
<b>Potassium imbalance</b>		
Hyperkalaemia	3	0
Hypokalaemia	3	0
Hypokalaemic syndrome	1	0
<b>Sodium imbalance</b>		
Hyponatraemia	7	0
Hyponatraemic syndrome	3	0
<b>Sugar intolerance (excl glucose intolerance)</b>		
Lactose intolerance	1	0
<b>Total fluid volume decreased</b>		
Dehydration	130	0
<b>Total fluid volume increased</b>		
Fluid retention	37	0
Hypervolaemia	1	0
<b>Vitamin deficiencies NEC</b>		
Hypovitaminosis	3	0
<b>Water soluble vitamin deficiencies</b>		
Folate deficiency	3	0
Vitamin B12 deficiency	3	0
<b>Metabolic disorders SOC TOTAL</b>	<b>1572</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i><b>Arthropathies NEC</b></i>		
Arthritis	181	0
Arthropathy	22	0
Autoimmune arthritis	4	0
Haemarthrosis	5	0
Joint microhaemorrhage	1	0
Palindromic rheumatism	1	0
Polyarthritis	13	0
Rheumatic fever	1	0
Sacroiliitis	4	0
Seronegative arthritis	2	0
<i><b>Bone disorders NEC</b></i>		
Jaw disorder	3	0
Medial tibial stress syndrome	4	0
Osteitis	3	0
Osteonecrosis of jaw	3	0
Spinal disorder	1	0
<i><b>Bone related signs and symptoms</b></i>		
Bone pain	263	0
Bone swelling	5	0
Coccydynia	3	0
Metatarsalgia	1	0
Pain in jaw	255	0
Pubic pain	2	0
Spinal pain	47	0
<i><b>Bursal disorders</b></i>		
Bursitis	47	0
<i><b>Cartilage disorders</b></i>		
Chondritis	1	0
Costochondritis	45	0
Osteochondritis	1	0
Polychondritis	3	0
<i><b>Connective tissue disorders NEC</b></i>		
Connective tissue disorder	1	0
Polymyalgia rheumatica	43	0
Reynold's syndrome	1	0
Sjogren's syndrome	5	0
<i><b>Crystal arthropathic disorders</b></i>		
Chondrocalcinosis pyrophosphate	2	0
Crystal arthropathy	1	0
<i><b>Epiphyseal disorders</b></i>		
Epiphyses premature fusion	1	0
<i><b>Extremity deformities</b></i>		
Bone deformity	1	0
Finger deformity	1	0
Foot deformity	1	0
Hand deformity	2	0
Knee deformity	1	0
Limb deformity	4	0
Musculoskeletal deformity	1	0
<i><b>Intervertebral disc disorders NEC</b></i>		
Intervertebral disc protrusion	2	0
<i><b>Joint related disorders NEC</b></i>		

## Case Series Drug Analysis Print

### Name: COVID-19 mRNA Pfizer- BioNTech Vaccine Analysis Print

Report Run Date: 29-Jul-2021  
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 28-Jul-2021 18:30:14  
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
Chondromalacia	1	0
Joint deposit	1	0
Joint destruction	1	0
Joint laxity	3	0
Joint lock	19	0
Patellofemoral pain syndrome	1	0
Periarthritis	96	0
Rotator cuff syndrome	15	0
Temporomandibular joint syndrome	7	0
<b>Joint related signs and symptoms</b>		
Arthralgia	6347	0
Jaw clicking	4	0
Joint effusion	13	0
Joint noise	24	0
Joint range of motion decreased	16	0
Joint stiffness	164	0
Joint swelling	349	0
Joint vibration	2	0
Joint warmth	11	0
Loose body in joint	1	0
<b>Ligament disorders</b>		
Symphysiolysis	1	0
<b>Lupus erythematosus (incl subtypes)</b>		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	17	0
<b>Metabolic bone disorders</b>		
Osteopenia	1	0
Osteoporosis	1	0
<b>Muscle infections and inflammations</b>		
Antisynthetase syndrome	3	0
Myositis	20	0
Polymyositis	5	0
<b>Muscle pains</b>		
Fibromyalgia	71	0
Myalgia	8005	0
Myalgia intercostal	1	0
Myofascial pain syndrome	6	0
<b>Muscle related signs and symptoms NEC</b>		
Haematoma muscle	1	0
Muscle atrophy	15	0
Muscle discomfort	2	0
Muscle disorder	3	0
Muscle fatigue	256	0
Muscle haemorrhage	1	0
Muscle mass	4	0
Muscle oedema	1	0
Muscle spasms	1265	0
Muscle swelling	19	0
Muscle tightness	62	0
Muscle twitching	300	0
<b>Muscle tone abnormalities</b>		
Muscle rigidity	12	0
Nuchal rigidity	10	0

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Muscle &amp; tissue disorders cont'd</i>		
Torticollis	3	0
Trismus	27	0
<b>Muscle weakness conditions</b>		
Muscular weakness	619	0
<b>Musculoskeletal and connective tissue conditions NEC</b>		
Back disorder	2	0
Growth disorder	1	0
Limb mass	15	0
Mandibular mass	2	0
Mastication disorder	3	0
Mobility decreased	66	0
Musculoskeletal disorder	10	0
Musculoskeletal stiffness	873	0
Posture abnormal	1	0
Weight bearing difficulty	1	0
<b>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</b>		
Head deformity	2	0
<b>Musculoskeletal and connective tissue infections and inflammations NEC</b>		
Dactylitis	2	0
Dupuytren's contracture	1	0
Fasciitis	1	0
Plantar fasciitis	6	0
<b>Musculoskeletal and connective tissue pain and discomfort</b>		
Back pain	1626	0
Flank pain	36	0
Limb discomfort	1084	0
Musculoskeletal chest pain	144	0
Musculoskeletal discomfort	70	0
Musculoskeletal pain	34	0
Neck pain	1294	0
Pain in extremity	9043	0
Rheumatic disorder	9	0
<b>Myopathies</b>		
Myopathy	4	0
Rhabdomyolysis	7	0
<b>Osteoarthropathies</b>		
Nodal osteoarthritis	1	0
Osteoarthritis	30	0
Spinal osteoarthritis	1	0
<b>Psoriatic arthropathies</b>		
Psoriatic arthropathy	14	0
<b>Rheumatoid arthropathies</b>		
Rheumatoid arthritis	84	0
<b>Soft tissue disorders NEC</b>		
Axillary mass	173	0
Fluctuance	1	0
Groin pain	82	0
Neck mass	22	0
Purple glove syndrome	1	0
Soft tissue disorder	2	0
Soft tissue swelling	3	0
<b>Spine and neck deformities</b>		

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Muscle &amp; tissue disorders cont'd</i>		
Kyphosis	2	0
Lordosis	1	0
Neck deformity	1	0
Scoliosis	1	0
<b><i>Spondyloarthropathies</i></b>		
Ankylosing spondylitis	6	0
Arthritis reactive	27	0
Spondylitis	1	0
<b><i>Synovial disorders</i></b>		
Synovial cyst	15	0
Synovitis	4	0
<b><i>Tendon disorders</i></b>		
Enthesopathy	1	0
Tendon disorder	2	0
Tendon pain	16	0
Tendonitis	26	0
Tenosynovitis	2	0
Tenosynovitis stenosaurs	2	0
Trigger finger	19	0
<b><i>Trunk deformities</i></b>		
Drooping shoulder syndrome	1	0
Shoulder deformity	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>33674</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i>B-cell lymphomas NEC</i>		
Follicular lymphoma	3	0
<i>Bone neoplasms unspecified malignancy</i>		
Bone neoplasm	1	0
<i>Breast and nipple neoplasms benign</i>		
Benign breast neoplasm	1	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	28	0
Breast cancer female	1	0
Breast cancer male	1	0
Breast cancer stage I	1	0
Breast cancer stage III	1	0
Invasive ductal breast carcinoma	1	0
Triple negative breast cancer	2	0
<i>Cardiovascular neoplasms benign</i>		
Pericardial lipoma	1	0
<i>Colorectal neoplasms malignant</i>		
Colon cancer	1	0
Colorectal cancer	1	0
Rectal cancer	1	0
<i>Endocrine neoplasms malignant and unspecified NEC</i>		
Neuroendocrine tumour	1	0
Thyroid neoplasm	1	0
<i>Endometrial neoplasms malignant</i>		
Endometrial cancer	2	0
<i>Follicular lymphomas</i>		
Primary gastrointestinal follicular lymphoma	1	0
<i>Gastric neoplasms malignant</i>		
Gastric cancer	1	1
<i>Gastrointestinal neoplasms malignant NEC</i>		
Gastrointestinal carcinoma	3	0
<i>Hodgkin's disease NEC</i>		
Hodgkin's disease	3	0
<i>Islet cell neoplasms and APUDoma NEC</i>		
Pancreatic neuroendocrine tumour	1	0
<i>Leukaemias NEC</i>		
Leukaemia	1	0
<i>Leukaemias acute NEC</i>		
Acute leukaemia	1	0
<i>Leukaemias chronic lymphocytic</i>		
Chronic lymphocytic leukaemia	2	0
<i>Lip and oral cavity neoplasms malignant</i>		
Lip and/or oral cavity cancer recurrent	1	0
<i>Lymphomas unspecified NEC</i>		
Lymphoma	20	1
<i>Metastases to specified sites</i>		
Metastases to liver	1	0
Metastases to lymph nodes	5	0
<i>Metastases to unknown and unspecified sites</i>		
Metastasis	1	0
<i>Myelodysplastic syndromes</i>		
Myelodysplastic syndrome	2	0
<i>Myeloproliferative disorders (excl leukaemias)</i>		

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Reaction Name	Total	Fatal
<b>Neoplasms</b> Neoplasms cont'd		
Essential thrombocythaemia	1	0
<b>Neoplasms benign site unspecified NEC</b>		
Adenoma benign	1	0
<b>Neoplasms malignant site unspecified NEC</b>		
Adenocarcinoma metastatic	1	0
Neoplasm malignant	5	0
Second primary malignancy	1	0
Squamous cell carcinoma	3	0
<b>Neoplasms unspecified malignancy and site unspecified NEC</b>		
Neoplasm	1	0
Neoplasm recurrence	1	0
<b>Nervous system neoplasms benign NEC</b>		
Cranial nerve neoplasm benign	1	0
Neurilemmoma benign	1	0
<b>Nervous system neoplasms unspecified malignancy NEC</b>		
Brain neoplasm	2	0
<b>Neuromas</b>		
Acoustic neuroma	2	0
<b>Non-Hodgkin's lymphomas NEC</b>		
Non-Hodgkin's lymphoma	2	0
<b>Oesophageal neoplasms malignant</b>		
Oesophageal cancer metastatic	4	0
<b>Oncologic complications and emergencies</b>		
Cancer pain	1	0
<b>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</b>		
Tonsil cancer	2	0
<b>Pancreatic neoplasms malignant (excl islet cell and carcinoid)</b>		
Pancreatic carcinoma	4	0
<b>Plasma cell myelomas</b>		
POEMS syndrome	1	0
Plasma cell myeloma	1	0
<b>Plasma cell neoplasms NEC</b>		
TEMPI syndrome	1	0
<b>Prostatic neoplasms malignant</b>		
Prostate cancer	3	0
<b>Renal neoplasms malignant</b>		
Renal cancer	2	0
<b>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</b>		
Bronchial carcinoma	1	0
Lung neoplasm malignant	6	0
<b>Skin melanomas (excl ocular)</b>		
Malignant melanoma	1	0
<b>Skin neoplasms benign</b>		
Acrochordon	2	0
Anogenital warts	4	0
Haemangioma of skin	3	0
Melanocytic naevus	4	0
Skin papilloma	10	0
<b>Skin neoplasms malignant and unspecified (excl melanoma)</b>		
Basal cell carcinoma	2	0
Bowen's disease	1	0



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Reaction Name	Total	Fatal
<b>Neoplasms</b> Neoplasms cont'd		
Neoplasm skin	1	0
Squamous cell carcinoma of skin	1	0
<b><i>Soft tissue neoplasms benign NEC</i></b>		
Lipoma	5	0
Lymphangioma	1	0
<b><i>Soft tissue sarcomas histology unspecified</i></b>		
Sarcoma	1	0
<b><i>Thyroid neoplasms malignant</i></b>		
Papillary thyroid cancer	2	0
Thyroid cancer	1	0
<b><i>Uterine neoplasms benign</i></b>		
Uterine leiomyoma	8	0
<b>Neoplasms SOC TOTAL</b>	<b>186</b>	<b>2</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i><b>Abnormal reflexes</b></i>		
Areflexia	5	0
Extensor plantar response	1	0
Hyperreflexia	3	0
Hyporeflexia	7	0
<i><b>Abnormal sleep-related events</b></i>		
Sleep paralysis	17	0
<i><b>Absence seizures</b></i>		
Petit mal epilepsy	21	0
<i><b>Acute polyneuropathies</b></i>		
Guillain-Barre syndrome	39	0
Subacute inflammatory demyelinating polyneuropathy	1	0
<i><b>Autonomic nervous system disorders</b></i>		
Anticholinergic syndrome	1	0
Autonomic nervous system imbalance	6	0
Autonomic neuropathy	1	0
Horner's syndrome	1	0
<i><b>Central nervous system aneurysms and dissections</b></i>		
Intracranial aneurysm	2	1
Vertebral artery dissection	1	0
<i><b>Central nervous system haemorrhages and cerebrovascular accidents</b></i>		
Brain stem infarction	1	1
Brain stem stroke	1	0
Carotid artery thrombosis	3	0
Cerebellar haemorrhage	2	0
Cerebellar infarction	2	0
Cerebellar ischaemia	1	0
Cerebellar stroke	4	0
Cerebral artery embolism	3	1
Cerebral artery occlusion	1	0
Cerebral artery thrombosis	3	0
Cerebral haemorrhage	35	7
Cerebral infarction	23	1
Cerebral thrombosis	9	0
Cerebrovascular accident	305	13
Embolic stroke	6	0
Haemorrhage intracranial	9	2
Haemorrhagic cerebral infarction	1	0
Haemorrhagic stroke	9	4
Internal capsule infarction	1	0
Intracranial haematoma	1	0
Ischaemic cerebral infarction	1	0
Ischaemic stroke	32	1
Lacunar infarction	2	0
Lacunar stroke	3	0
Lateral medullary syndrome	1	0
Pseudostroke	1	0
Subarachnoid haemorrhage	13	5
Thalamic infarction	1	0
Thrombotic stroke	2	0
<i><b>Central nervous system inflammatory disorders NEC</b></i>		
Gliosis	1	0
<i><b>Central nervous system vascular disorders NEC</b></i>		

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Brain hypoxia	1	1
Central nervous system vasculitis	1	0
Cerebral amyloid angiopathy	1	0
Cerebral congestion	2	0
Cerebral small vessel ischaemic disease	1	0
Cerebrovascular disorder	1	0
Post cardiac arrest syndrome	1	1
Reversible cerebral vasoconstriction syndrome	1	0
<b>Cerebrovascular venous and sinus thrombosis</b>		
Cerebral venous sinus thrombosis	32	2
Cerebral venous thrombosis	4	0
Superior sagittal sinus thrombosis	3	0
Transverse sinus thrombosis	1	0
<b>Cervical spinal cord and nerve root disorders</b>		
Cervicobrachial syndrome	3	0
<b>Choreiform movements</b>		
Chorea	2	0
<b>Chronic polyneuropathies</b>		
Demyelinating polyneuropathy	1	0
<b>Coma states</b>		
Coma	8	0
Diabetic coma	1	0
Hypoglycaemic coma	1	0
<b>Coordination and balance disturbances</b>		
Ataxia	9	0
Balance disorder	271	0
Coordination abnormal	35	0
Dysdiadochokinesis	1	0
Dysstasia	37	0
Nystagmus	10	0
<b>Cortical dysfunction NEC</b>		
Alexia	1	0
Aphasia	52	0
Apraxia	1	0
Dyspraxia	1	0
Neurologic neglect syndrome	1	0
Sensory processing disorder	2	0
Visuospatial deficit	1	0
<b>Cranial nerve disorders NEC</b>		
Cranial nerve disorder	2	0
<b>Dementia (excl Alzheimer's type)</b>		
Dementia	11	0
Dementia with Lewy bodies	1	0
Senile dementia	1	0
<b>Demyelinating disorders NEC</b>		
Acute disseminated encephalomyelitis	4	0
Clinically isolated syndrome	1	0
Demyelination	8	0
Neuromyelitis optica spectrum disorder	1	0
<b>Disturbances in consciousness NEC</b>		
Altered state of consciousness	10	0
Consciousness fluctuating	2	0
Depressed level of consciousness	34	1

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
Nervous system disorders cont'd		
Infant sedation	1	0
Lethargy	1667	0
Loss of consciousness	421	0
Postictal state	2	0
Sedation	7	0
Somnolence	739	0
Stupor	4	0
Syncope	1427	0
<b>Disturbances in sleep phase rhythm</b>		
Irregular sleep phase	2	0
Irregular sleep wake rhythm disorder	1	0
<b>Dyskinesias and movement disorders NEC</b>		
Akathisia	3	0
Bradykinesia	11	0
Clumsiness	13	0
Dyskinesia	47	0
Extrapyramidal disorder	2	0
Fine motor skill dysfunction	7	0
Foetal movement disorder	1	0
Hyperkinesia	3	0
Hypokinesia	50	0
Motor dysfunction	2	0
Movement disorder	37	0
Psychomotor hyperactivity	17	0
Synkinesis	2	0
Tardive dyskinesia	2	0
<b>Dystonias</b>		
Dystonia	15	0
Writer's cramp	1	0
<b>Encephalitis NEC</b>		
Encephalitis autoimmune	1	0
Limbic encephalitis	1	0
Noninfective encephalitis	4	0
<b>Encephalopathies NEC</b>		
Encephalopathy	3	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	5	0
IVth nerve paralysis	1	0
Microvascular cranial nerve palsy	1	0
VIth nerve paralysis	9	0
<b>Facial cranial nerve disorders</b>		
Bell's palsy	355	0
Facial nerve disorder	8	0
Facial paralysis	280	0
Facial paresis	73	0
Facial spasm	32	0
<b>Generalised tonic-clonic seizures</b>		
Generalised tonic-clonic seizure	33	0
<b>Headaches NEC</b>		
Cervicogenic headache	3	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
Nervous system disorders cont'd		
Cluster headache	158	0
Cold-stimulus headache	13	0
Drug withdrawal headache	2	0
Exertional headache	7	0
External compression headache	1	0
Headache	19277	0
Medication overuse headache	2	0
New daily persistent headache	4	0
Occipital neuralgia	8	0
Ophthalmoplegic migraine	1	0
Primary cough headache	4	0
Primary headache associated with sexual activity	3	0
Sinus headache	267	0
Tension headache	404	0
Thunderclap headache	6	0
Vascular headache	13	0
<b>Hydrocephalic conditions</b>		
Hydrocephalus	2	0
<b>Hypoglossal nerve disorders</b>		
Tongue paralysis	1	0
<b>Increased intracranial pressure disorders</b>		
Brain compression	1	0
Brain oedema	4	0
Idiopathic intracranial hypertension	6	0
Intracranial pressure increased	1	0
<b>Intellectual disabilities</b>		
Intellectual disability	2	0
<b>Lumbar spinal cord and nerve root disorders</b>		
Sciatica	61	0
<b>Memory loss (excl dementia)</b>		
Amnesia	110	0
Memory impairment	118	0
Transient global amnesia	7	0
<b>Mental impairment (excl dementia and memory loss)</b>		
Cognitive disorder	60	0
Cognitive linguistic deficit	1	0
Disturbance in attention	220	0
Mental impairment	34	0
<b>Migraine headaches</b>		
Hemiplegic migraine	18	0
Migraine	2031	0
Migraine with aura	137	0
Migraine without aura	15	0
Ophthalmic migraine	4	0
Retinal migraine	22	0
Typical aura without headache	6	0
Vestibular migraine	14	0
<b>Mixed cranial nerve disorders</b>		
Bulbar palsy	2	0
<b>Mononeuropathies</b>		
Carpal tunnel syndrome	15	0
Cubital tunnel syndrome	1	0
Meralgia paraesthetica	1	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
Nervous system disorders cont'd		
Mononeuritis	2	0
Mononeuropathy	2	0
Nerve compression	14	0
Peripheral nerve lesion	1	0
Peroneal nerve palsy	11	0
Sciatic nerve neuropathy	2	0
Ulnar neuritis	1	0
Ulnar tunnel syndrome	1	0
<b>Motor neurone diseases</b>		
Motor neurone disease	1	0
<b>Multiple sclerosis acute and progressive</b>		
Band sensation	1	0
Multiple sclerosis	24	0
Multiple sclerosis relapse	20	0
Tumefactive multiple sclerosis	1	1
<b>Muscle tone abnormal</b>		
Hypotonia	13	0
Muscle tone disorder	1	0
Serotonin syndrome	1	0
Stiff leg syndrome	1	0
<b>Myelitis (incl infective)</b>		
Myelitis transverse	25	0
<b>Narcolepsy and hypersomnia</b>		
Cataplexy	1	0
Hypersomnia	76	0
Narcolepsy	6	0
<b>Nervous system disorders NEC</b>		
Central nervous system lesion	2	0
Cerebral disorder	1	0
Nervous system disorder	7	0
Neurotoxicity	1	0
<b>Neurologic visual problems NEC</b>		
Hemianopia	1	0
Hemianopia homonymous	1	0
Quadrantanopia	1	0
Tunnel vision	12	0
<b>Neurological signs and symptoms NEC</b>		
Clonus	3	0
Decerebrate posture	1	0
Dizziness	7101	0
Dizziness exertional	34	0
Dizziness postural	553	0
Droping	20	0
Fontanelle bulging	2	0
Head discomfort	218	0
Hyporesponsive to stimuli	2	0
Inability to crawl	2	0
Infant irritability	6	0
Myoclonus	20	0
Neurological symptom	34	0
Patient elopement	1	0
Persistent postural-perceptual dizziness	12	0
Presyncope	444	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
Nervous system disorders cont'd		
Sensory overload	2	0
Slow response to stimuli	2	0
Tongue biting	4	0
Unresponsive to stimuli	35	0
<b>Neuromuscular disorders NEC</b>		
Muscle contractions involuntary	16	0
Muscle spasticity	9	0
Neuromuscular pain	3	0
<b>Neuromuscular junction dysfunction</b>		
Myasthenia gravis	7	0
Myasthenia gravis crisis	2	0
<b>Olfactory nerve disorders</b>		
Anosmia	182	0
Hyposmia	14	0
Parosmia	178	0
<b>Optic nerve disorders NEC</b>		
Optic neuritis	20	0
<b>Paraesthesias and dysaesthesias</b>		
Burning feet syndrome	5	0
Burning sensation	374	0
Burning sensation mucosal	2	0
Dysaesthesia	5	0
Formication	32	0
Hand-arm vibration syndrome	3	0
Hemianaesthesia	1	0
Hemiparaesthesia	2	0
Hyperaesthesia	68	0
Hypoaesthesia	2047	0
Paraesthesia	2851	0
Reversed hot-cold sensation	3	0
Synaesthesia	1	0
<b>Paralysis and paresis (excl cranial nerve)</b>		
Diplegia	9	1
Hemiparesis	35	0
Hemiplegia	28	0
Locked-in syndrome	1	0
Monoparesis	45	0
Monoplegia	51	0
Paralysis	92	0
Paraparesis	3	0
Paresis	6	0
Quadriparesis	1	0
<b>Parkinson's disease and parkinsonism</b>		
Freezing phenomenon	8	0
Parkinson's disease	3	0
Parkinsonian gait	1	0
Parkinsonism	4	0
Reduced facial expression	7	0
<b>Partial complex seizures</b>		
Dreamy state	6	0
Focal dyscognitive seizures	2	0
Temporal lobe epilepsy	2	0
<b>Partial simple seizures NEC</b>		

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
Nervous system disorders cont'd		
Autonomic seizure	1	0
<b>Peripheral neuropathies NEC</b>		
Neuralgic amyotrophy	1	0
Neuritis	5	0
Neuropathy peripheral	69	0
Peripheral sensory neuropathy	7	0
Thoracic outlet syndrome	1	0
<b>Seizures and seizure disorders NEC</b>		
Atonic seizures	4	0
Change in seizure presentation	1	0
Clonic convulsion	3	0
Convulsions local	1	0
Epilepsy	126	0
Epileptic aura	2	0
Epileptic encephalopathy	1	0
Febrile convulsion	14	0
Partial seizures	17	0
Post stroke seizure	1	0
Psychogenic seizure	6	0
Seizure	409	0
Seizure anoxic	1	0
Seizure cluster	5	0
Seizure like phenomena	1	0
Status epilepticus	35	0
Tonic clonic movements	2	0
Tonic convulsion	17	0
Tonic posturing	1	0
<b>Sensory abnormalities NEC</b>		
Ageusia	379	0
Allodynia	15	0
Aura	13	0
Complex regional pain syndrome	3	0
Dysgeusia	943	0
Electric shock sensation	25	0
Hypergeusia	1	0
Hypogeusia	3	0
Intercostal neuralgia	1	0
Loss of proprioception	3	0
Neuralgia	363	0
Persistent genital arousal disorder	1	0
Phantom limb syndrome	4	0
Post herpetic neuralgia	14	0
Restless arm syndrome	2	0
Restless legs syndrome	90	0
Sensory disturbance	64	0
Sensory loss	55	0
Taste disorder	199	0
Visual perseveration	2	0
<b>Sleep disturbances NEC</b>		
Sleep deficit	3	0
Sudden onset of sleep	1	0
<b>Speech and language abnormalities</b>		
Dysarthria	133	0



## Case Series Drug Analysis Print

### Name: COVID-19 mRNA Pfizer- BioNTech Vaccine Analysis Print

Report Run Date: 29-Jul-2021

Data Lock Date: 28-Jul-2021 18:30:14

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Incoherent	9	0
Language disorder	1	0
Repetitive speech	2	0
Slow speech	10	0
Speech disorder	46	0
<b>Spinal cord and nerve root disorders NEC</b>		
Radiculitis brachial	7	0
Radiculopathy	4	0
<b>Structural brain disorders NEC</b>		
Brain injury	5	2
Hyperintensity in brain deep nuclei	1	0
<b>Transient cerebrovascular events</b>		
Transient ischaemic attack	120	2
<b>Tremor (excl congenital)</b>		
Action tremor	1	0
Essential tremor	3	0
Head titubation	8	0
Resting tremor	2	0
Tremor	1149	0
<b>Trigeminal disorders</b>		
Facial neuralgia	14	0
Numb chin syndrome	2	0
Trigeminal nerve disorder	2	0
Trigeminal neuralgia	35	0
<b>Vagus nerve disorders</b>		
Vocal cord paralysis	1	0
<b>Vertigos NEC</b>		
Cervicogenic vertigo	1	0
Vertigo CNS origin	1	0
<b>Nervous system disorders SOC TOTAL</b>	<b>48833</b>	<b>47</b>

## Case Series Drug Analysis Print

### Name: COVID-19 mRNA Pfizer- BioNTech Vaccine Analysis Print

Report Run Date: 29-Jul-2021  
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 28-Jul-2021 18:30:14  
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i>Abortions not specified as induced or spontaneous</i>		
Abortion missed	2	0
<i>Abortions spontaneous</i>		
Abortion spontaneous	217	2
Abortion threatened	2	0
<i>Amniotic fluid and cavity disorders of pregnancy NEC</i>		
Amniorrhoea	1	0
<i>Foetal complications NEC</i>		
Foetal hypokinesia	4	0
<i>Foetal growth complications</i>		
Foetal growth restriction	1	0
<i>Foetal position and presentation abnormalities</i>		
Oblique presentation	1	0
<i>Gestational age and weight conditions</i>		
Premature baby	2	1
Term baby	1	0
<i>Haemorrhagic complications of pregnancy</i>		
Haemorrhage in pregnancy	1	0
Premature separation of placenta	2	0
Subchorionic haematoma	1	0
Subchorionic haemorrhage	1	0
<i>Labour onset and length abnormalities</i>		
Premature delivery	1	0
Premature labour	2	0
Premature rupture of membranes	1	0
Threatened labour	1	0
<i>Maternal complications of labour NEC</i>		
Uterine contractions abnormal	1	0
Uterine hypertonus	5	0
<i>Maternal complications of pregnancy NEC</i>		
Decidual cast	4	0
Ectopic pregnancy	2	0
Morning sickness	8	0
Preterm premature rupture of membranes	3	0
Somatic symptom disorder of pregnancy	3	0
<i>Neonatal hepatobiliary disorders</i>		
Jaundice neonatal	1	0
<i>Newborn complications NEC</i>		
Neonatal disorder	1	0
<i>Normal newborn status</i>		
Normal newborn	1	0
<i>Normal pregnancy, labour and delivery</i>		
Labour pain	1	0
Live birth	1	0
Pregnancy	36	0
Uterine contractions during pregnancy	1	0
<i>Placental abnormalities (excl neoplasms)</i>		
Placental disorder	1	0
<i>Postpartum complications NEC</i>		
Postpartum haemorrhage	4	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	2	0
Peripartum cardiomyopathy	1	0

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Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
Pregnancy conditions cont'd		
<b><i>Stillbirth and foetal death</i></b>		
Foetal death	3	2
Stillbirth	3	2
<b><i>Unintended pregnancies</i></b>		
Pregnancy after post coital contraception	2	0
Pregnancy on contraceptive	2	0
Pregnancy on oral contraceptive	1	0
Pregnancy with contraceptive device	1	0
Unintended pregnancy	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>330</b>	<b>7</b>

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<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 pacing issue	1	0
Device stimulation issue	1	0
Oversensing	14	0
Thrombosis in device	7	0
<b><i>Device physical property and chemical issues</i></b>		
Device breakage	1	0
Device defective	7	0
Device kink	1	0
Needle issue	2	0
<b><i>Product contamination and sterility issues</i></b>		
Product contamination	10	0
Product contamination physical	2	0
<b><i>Product packaging issues</i></b>		
Product closure issue	1	0
<b><i>Product physical issues</i></b>		
Liquid product physical issue	7	0
Product odour abnormal	1	0
Product physical issue	2	0
Product taste abnormal	9	0
<b><i>Product quality issues NEC</i></b>		
Product complaint	1	0
Product origin unknown	6	0
<b><i>Product supply and availability issues</i></b>		
Product availability issue	1	0
<b>null SOC TOTAL</b>	<b>79</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	16	0
Behaviour disorder	1	0
Breath holding	6	0
Sexually inappropriate behaviour	1	0
Staring	5	0
<b><i>Adjustment disorders</i></b>		
Adjustment disorder with depressed mood	2	0
<b><i>Affect alterations NEC</i></b>		
Affect lability	8	0
Constricted affect	2	0
Flat affect	4	0
Inappropriate affect	13	0
<b><i>Amnesic symptoms</i></b>		
Paramnesia	4	0
<b><i>Anxiety disorders NEC</i></b>		
Generalised anxiety disorder	1	0
Neurosis	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	60	0
Anxiety	542	0
Immunisation anxiety related reaction	1	0
Nervousness	130	0
Stress	62	0
Tension	28	0
<b><i>Attention deficit and disruptive behaviour disorders</i></b>		
Attention deficit hyperactivity disorder	3	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Aggression	8	0
Aversion	1	0
Disinhibition	1	0
Indifference	6	0
Paranoia	16	0
Personality change	3	0
Social avoidant behaviour	5	0
Soliloquy	2	0
Suspiciousness	1	0
<b><i>Bipolar disorders</i></b>		
Bipolar I disorder	2	0
Bipolar disorder	4	0
<b><i>Cognitive and attention disorders and disturbances NEC</i></b>		
Daydreaming	7	0
Distractibility	1	0
Mental fatigue	164	0
<b><i>Communications disorders</i></b>		
Communication disorder	5	0
Mutism	2	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	632	0
Disorientation	199	0
<b><i>Decreased physical activity levels</i></b>		
Catatonia	1	0
<b><i>Deliria</i></b>		

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Delirium	80	0
<b>Delusional symptoms</b>		
Delusion	9	0
<b>Depressive disorders</b>		
Agitated depression	3	0
Depression	220	0
Depression suicidal	7	0
Major depression	5	0
Mixed anxiety and depressive disorder	1	0
<b>Dissociative states</b>		
Depersonalisation/derealisation disorder	7	0
Dissociation	21	0
Dissociative amnesia	2	0
Dissociative disorder	2	0
<b>Disturbances in initiating and maintaining sleep</b>		
Initial insomnia	16	0
Insomnia	914	0
Middle insomnia	23	0
Terminal insomnia	27	0
<b>Dyssomnias</b>		
Dyssomnia	1	0
Poor quality sleep	150	0
<b>Eating disorders NEC</b>		
Bulimia nervosa	1	0
Eating disorder	9	0
Selective eating disorder	1	0
<b>Emotional and mood disturbances NEC</b>		
Anger	26	0
Dysphoria	2	0
Emotional disorder	41	0
Emotional distress	32	0
Emotional poverty	1	0
Euphoric mood	34	0
Frustration tolerance decreased	3	0
Irritability	148	0
Mood altered	41	0
<b>Factitious disorders</b>		
Factitious disorder	2	0
<b>Fear symptoms and phobic disorders (incl social phobia)</b>		
Agoraphobia	1	0
Fear	13	0
Fear of falling	3	0
Fear of injection	4	0
Osmophobia	1	0
Phobia	2	0
Phonophobia	2	0
Social anxiety disorder	1	0
Social fear	1	0
<b>Fluctuating mood symptoms</b>		
Mood swings	89	0
<b>Hallucinations (excl sleep-related)</b>		
Hallucination	141	0
Hallucination, auditory	12	0

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Hallucination, olfactory	9	0
Hallucination, tactile	1	0
Hallucination, visual	21	0
Hallucinations, mixed	2	0
<b>Increased physical activity levels</b>		
Restlessness	108	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	13	0
Mental status changes	1	0
<b>Mood alterations with depressive symptoms</b>		
Anhedonia	2	0
Decreased interest	7	0
Depressed mood	252	0
Depressive symptom	1	0
Feeling of despair	3	0
Feelings of worthlessness	1	0
Negative thoughts	1	0
Psychomotor retardation	1	0
Sense of a foreshortened future	2	0
Tearfulness	30	0
<b>Mood alterations with manic symptoms</b>		
Hypomania	2	0
Mania	9	0
<b>Mood disorders NEC</b>		
Affective disorder	1	0
Apathy	19	0
Boredom	1	0
Laziness	1	0
Listless	14	0
<b>Narcolepsy and associated conditions</b>		
Hypnagogic hallucination	3	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	4	0
Female orgasmic disorder	2	0
Orgasm abnormal	3	0
Orgasmic sensation decreased	1	0
Premature ejaculation	1	0
<b>Panic attacks and disorders</b>		
Panic attack	120	0
Panic disorder	3	0
Panic reaction	19	0
<b>Parasomnias</b>		
Abnormal dreams	134	0
Abnormal sleep-related event	1	0

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Confusional arousal	1	0
Exploding head syndrome	1	0
Nightmare	145	0
Parasomnia	1	0
Sleep inertia	1	0
Sleep talking	4	0
Sleep terror	15	0
Somnambulism	4	0
<b>Perception disturbances NEC</b>		
Autoscopy	12	0
Deja vu	2	0
Derealisation	7	0
Flashback	3	0
Illusion	1	0
Near death experience	1	0
Time perception altered	1	0
<b>Personality disorders NEC</b>		
Personality disorder	1	0
<b>Pervasive developmental disorders NEC</b>		
Autism spectrum disorder	2	0
<b>Psychiatric elimination disorders</b>		
Enuresis	16	0
<b>Psychiatric symptoms NEC</b>		
Hypervigilance	8	0
Psychiatric symptom	3	0
Psychological trauma	1	0
Trance	1	0
<b>Psychotic disorder NEC</b>		
Psychotic behaviour	1	0
Psychotic disorder	15	0
<b>Schizophrenia NEC</b>		
Schizophrenia	1	0
<b>Sexual arousal disorders</b>		
Disturbance in sexual arousal	2	0
<b>Sexual desire disorders</b>		
Libido decreased	6	0
Libido increased	4	0
Loss of libido	10	0
<b>Sleep disorders NEC</b>		
Sleep disorder	146	0
Sleep disorder due to general medical condition, insomnia type	2	0
<b>Somatic symptom disorders</b>		
Conversion disorder	13	0
Habit cough	13	0
Somatic symptom disorder	1	0
Vomiting psychogenic	1	0
<b>Speech and language usage disturbances</b>		
Disorganised speech	6	0
Logorrhoea	2	0
<b>Speech articulation and rhythm disturbances</b>		
Dysphemia	18	0
Lack of spontaneous speech	1	0
Pressure of speech	1	0



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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
<i><b>Stereotypies and automatisms</b></i>		
Bruxism	10	0
Head banging	5	0
Stereotypy	1	0
<i><b>Stress disorders</b></i>		
Burnout syndrome	1	0
Post-traumatic stress disorder	2	0
<i><b>Substance related and addictive disorders</b></i>		
Alcohol problem	1	0
Alcoholic hangover	1	0
Alcoholism	2	0
Nicotine dependence	1	0
<i><b>Suicidal and self-injurious behaviour</b></i>		
Completed suicide	1	1
Intentional self-injury	6	0
Self-injurious ideation	2	0
Suicidal ideation	21	0
Suicide attempt	14	0
Suicide threat	1	0
<i><b>Thinking disturbances</b></i>		
Bradyphrenia	31	0
Intrusive thoughts	4	0
Morbid thoughts	1	0
Tachyphrenia	4	0
Thinking abnormal	15	0
Thought blocking	1	0
<i><b>Tic disorders</b></i>		
Tic	9	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>5459</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i><b>Bladder and urethral symptoms</b></i>		
Bladder discomfort	2	0
Bladder irritation	3	0
Bladder pain	19	0
Dysuria	39	0
Incontinence	20	0
Lower urinary tract symptoms	2	0
Micturition disorder	1	0
Micturition urgency	26	0
Pollakiuria	84	0
Urethral pain	5	0
Urge incontinence	1	0
Urinary hesitation	1	0
Urinary incontinence	43	0
Urinary retention	32	0
Urine flow decreased	8	0
<i><b>Bladder disorders NEC</b></i>		
Bladder disorder	5	0
Bladder fibrosis	1	0
Urinary bladder haemorrhage	2	0
<i><b>Bladder infections and inflammations</b></i>		
Cystitis interstitial	4	0
<i><b>Genital and urinary tract disorders NEC</b></i>		
Genitourinary symptom	1	0
Urinary tract disorder	3	0
<i><b>Glomerulonephritis and nephrotic syndrome</b></i>		
Glomerulonephritis	1	0
Glomerulonephritis minimal lesion	4	0
Glomerulonephritis rapidly progressive	1	0
IgA nephropathy	1	0
Nephrotic syndrome	15	0
<i><b>Myoneurogenic bladder disorders</b></i>		
Bladder dysfunction	5	0
Hypertonic bladder	1	0
Hypotonic urinary bladder	1	0
Loss of bladder sensation	1	0
Neurogenic bladder	1	0
<i><b>Nephritis NEC</b></i>		
Lupus nephritis	1	0
Nephritis	2	0
Tubulointerstitial nephritis	1	0
<i><b>Nephropathies and tubular disorders NEC</b></i>		
Nephropathy	1	0
<i><b>Renal disorders NEC</b></i>		
Renal disorder	4	1
Renal haemorrhage	1	0
Renal mass	1	0
<i><b>Renal failure and impairment</b></i>		
Acute kidney injury	36	4
Anuria	3	0
Chronic kidney disease	3	0
Oliguria	1	0
Renal failure	14	1

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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
Renal & urinary disorders cont'd		
Renal impairment	14	0
Renal injury	1	0
<b>Renal lithiasis</b>		
Nephrolithiasis	5	0
<b>Renal neoplasms</b>		
Renal cyst	1	0
<b>Renal obstructive disorders</b>		
Hydronephrosis	1	0
<b>Renal structural abnormalities and trauma</b>		
Kidney small	1	0
<b>Renal vascular and ischaemic conditions</b>		
Renal infarct	1	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	36	0
Haematuria	26	0
Proteinuria	6	0
Urine abnormality	8	0
Urine odour abnormal	5	0
<b>Urinary tract signs and symptoms NEC</b>		
Costovertebral angle tenderness	1	0
Cystitis-like symptom	1	0
Haemorrhage urinary tract	16	0
Nocturia	3	0
Polyuria	6	0
Renal colic	3	0
Renal pain	190	0
Urinary tract pain	2	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>732</b>	<b>7</b>

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Benign and malignant breast neoplasms</b></i>		
Breast cyst	8	0
<i><b>Breast disorders NEC</b></i>		
Breast disorder	1	0
Breast enlargement	13	0
Breast mass	78	0
Gynaecomastia	2	0
Mastoptosis	1	0
<i><b>Breast infections and inflammations</b></i>		
Breast inflammation	1	0
Nipple inflammation	1	0
<i><b>Breast signs and symptoms</b></i>		
Breast discharge	2	0
Breast discomfort	7	0
Breast engorgement	4	0
Breast haematoma	1	0
Breast oedema	4	0
Breast pain	394	0
Breast swelling	78	0
Breast tenderness	45	0
Nipple pain	26	0
Nipple swelling	3	0
<i><b>Cervix disorders NEC</b></i>		
Cervical dysplasia	2	0
Cervix disorder	1	0
Cervix haemorrhage uterine	2	0
Ectropion of cervix	2	0
<i><b>Cervix neoplasms</b></i>		
Cervical polyp	1	0
<i><b>Erection and ejaculation conditions and disorders</b></i>		
Ejaculation disorder	2	0
Ejaculation failure	1	0
Erectile dysfunction	32	0
Erection increased	2	0
Organic erectile dysfunction	7	0
Painful ejaculation	1	0
<i><b>Fallopian tube and ovary infections and inflammations</b></i>		
Noninfective oophoritis	1	0
<i><b>Lactation disorders</b></i>		
Breast milk discolouration	3	0
Breast milk odour abnormal	1	0
Galactorrhoea	5	0
Lactation disorder	3	0
Lactation puerperal increased	2	0
Suppressed lactation	16	0
<i><b>Menopausal effects NEC</b></i>		
Artificial menopause	1	0
Menopausal symptoms	11	0
Menopause delayed	1	0
Premature menopause	10	0
<i><b>Menopausal effects on the genitourinary tract</b></i>		
Atrophic vulvovaginitis	1	0
Postmenopausal haemorrhage	94	0

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Reproductive &amp; breast disorders cont'd</i>		
<b>Menstruation and uterine bleeding NEC</b>		
Abnormal uterine bleeding	5	0
Dysmenorrhoea	1598	0
Intermenstrual bleeding	624	0
Menstrual discomfort	14	0
Menstrual disorder	979	0
Menstruation irregular	1693	0
Premenstrual dysphoric disorder	5	0
Premenstrual headache	5	0
Premenstrual pain	60	0
Premenstrual syndrome	75	0
Withdrawal bleed	10	0
<b>Menstruation with decreased bleeding</b>		
Amenorrhoea	335	0
Hypomenorrhoea	393	0
Menstruation delayed	2758	0
Oligomenorrhoea	82	0
<b>Menstruation with increased bleeding</b>		
Heavy menstrual bleeding	3197	0
Menometrorrhagia	15	0
Polymenorrhoea	435	0
<b>Ovarian and fallopian tube cysts and neoplasms</b>		
Ovarian cyst	8	0
Polycystic ovaries	28	0
<b>Ovarian and fallopian tube disorders NEC</b>		
Adnexal torsion	1	0
Hydrosalpinx	2	0
Ovarian haemorrhage	4	0
Ovulation disorder	1	0
Ovulation pain	33	0
Premature ovulation	4	0
<b>Pelvis and broad ligament disorders NEC</b>		
Adnexa uteri pain	28	0
Pelvic floor muscle weakness	1	0
Pelvic haemorrhage	10	0
<b>Penile and scrotal infections and inflammations</b>		
Balanoposthitis	2	0
<b>Penile disorders NEC (excl erection and ejaculation)</b>		
Penile discomfort	1	0
Penile erythema	1	0
Penile haemorrhage	2	0
Penile pain	1	0
Penile size reduced	2	0
Penile swelling	4	0
Penis disorder	5	0
<b>Prostate and seminal vesicles infections and inflammations</b>		
Prostatitis	3	0
<b>Prostatic signs, symptoms and disorders NEC</b>		
Prostatic pain	1	0
Prostatomegaly	3	0
<b>Reproductive tract disorders NEC (excl neoplasms)</b>		
Genital haemorrhage	13	0
Genital hypoaesthesia	1	0

## Case Series Drug Analysis Print

### Name: COVID-19 mRNA Pfizer- BioNTech Vaccine Analysis Print

Report Run Date: 29-Jul-2021  
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 28-Jul-2021 18:30:14  
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
Genital lesion	1	0
Genital paraesthesia	1	0
Genital ulceration	5	0
<b>Reproductive tract infections and inflammations NEC</b>		
Genital tract inflammation	1	0
<b>Reproductive tract signs and symptoms NEC</b>		
Genital burning sensation	2	0
Genital pain	3	0
Genital rash	2	0
Genital swelling	2	0
Pelvic discomfort	4	0
Pelvic pain	70	0
Perineal pain	2	0
Pruritus genital	3	0
<b>Scrotal disorders NEC</b>		
Scrotal discomfort	1	0
Scrotal erythema	1	0
Scrotal exfoliation	1	0
Scrotal pain	6	0
Scrotal swelling	4	0
Varicocele	1	0
<b>Sexual function and fertility disorders NEC</b>		
Dyspareunia	3	0
Infertility	3	0
Sexual dysfunction	3	0
<b>Spermatogenesis and semen disorders</b>		
Aspermia	1	0
Haemospermia	6	0
Semen discolouration	1	0
<b>Testicular and epididymal disorders NEC</b>		
Testicular disorder	2	0
Testicular pain	30	0
Testicular swelling	5	0
Testis discomfort	1	0
<b>Uterine disorders NEC</b>		
Adenomyosis	5	0
Endometrial thickening	2	0
Endometriosis	56	0
Uterine haemorrhage	19	0
Uterine pain	10	0
<b>Uterine infections and inflammations (excl cervix)</b>		
Uterine inflammation	1	0
<b>Uterine neoplasms</b>		
Uterine polyp	4	0
<b>Uterine tone disorders</b>		
Uterine spasm	20	0
<b>Vulvovaginal cysts and neoplasms</b>		
Bartholin's cyst	1	0
Vaginal cyst	5	0
<b>Vulvovaginal disorders NEC</b>		
Vaginal haemorrhage	846	0
Vulval haemorrhage	15	0
Vulval ulceration	4	0

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
Reproductive & breast disorders cont'd		
Vulvovaginal ulceration	3	0
<b><i>Vulvovaginal signs and symptoms</i></b>		
Clitoral engorgement	1	0
Coital bleeding	2	0
Labia enlarged	1	0
Vaginal discharge	47	0
Vaginal odour	1	0
Vulval oedema	1	0
Vulvovaginal burning sensation	3	0
Vulvovaginal dryness	3	0
Vulvovaginal pain	16	0
Vulvovaginal pruritus	6	0
Vulvovaginal rash	1	0
Vulvovaginal swelling	2	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>14553</b>	<b>0</b>

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Apnoea	4	0
Apnoeic attack	1	0
Dyspnoea	2956	7
Dyspnoea at rest	9	0
Dyspnoea exertional	28	1
Hyperventilation	35	0
Hypopnoea	74	0
Hypoventilation	1	0
Irregular breathing	16	0
Mouth breathing	3	0
Nocturnal dyspnoea	1	0
Orthopnoea	3	0
Respiration abnormal	37	0
Respiratory arrest	11	0
Respiratory depression	1	0
Respiratory distress	15	0
Sleep apnoea syndrome	9	0
Tachypnoea	23	0
<i><b>Bronchial conditions NEC</b></i>		
Bronchial secretion retention	2	0
Bronchiectasis	11	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	238	0
Asthma late onset	2	0
Bronchospasm	12	0
Chronic obstructive pulmonary disease	14	1
Cough variant asthma	4	0
Obstructive airways disorder	7	0
Reversible airways obstruction	1	0
Wheezing	301	0
<i><b>Conditions associated with abnormal gas exchange</b></i>		
Asphyxia	1	0
Cyanosis central	1	0
Hyperoxia	1	0
Hypoxia	22	1
Respiratory acidosis	2	0
<i><b>Coughing and associated symptoms</b></i>		
Allergic cough	5	0
Cough	1714	2
Cough decreased	2	0
Haemoptysis	38	0
Productive cough	117	0
Sputum discoloured	4	0
Sputum increased	1	0
<i><b>Diaphragmatic disorders</b></i>		
Diaphragm muscle weakness	1	0
<i><b>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</b></i>		
Laryngeal disorder	1	0
Reflux laryngitis	1	0
Vocal cord disorder	1	0
<i><b>Laryngeal spasm, oedema and obstruction</b></i>		



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Reaction Name	Total	Fatal
<b>Respiratory disorders</b> Respiratory disorders cont'd		
Epiglottic oedema	1	0
Laryngeal obstruction	1	0
Laryngeal oedema	1	0
Laryngospasm	1	0
Stridor	18	0
<b>Lower respiratory tract inflammatory and immunologic conditions</b>		
Alveolitis	1	0
Hypersensitivity pneumonitis	1	0
Lower respiratory tract inflammation	1	0
Pneumonia aspiration	8	5
Pneumonitis	22	1
Pulmonary sarcoidosis	2	0
<b>Lower respiratory tract signs and symptoms</b>		
Hiccups	25	0
Increased bronchial secretion	1	0
Lung opacity	2	0
Pleuritic pain	15	0
Pulmonary haemorrhage	1	0
Pulmonary pain	63	0
Rales	4	0
Respiratory fremitus	1	0
<b>Nasal congestion and inflammations</b>		
Nasal congestion	199	0
Nasal inflammation	2	0
Rhinitis allergic	13	0
<b>Nasal disorders NEC</b>		
Epistaxis	693	0
Intranasal hypoaesthesia	1	0
Intranasal paraesthesia	1	0
Nasal crusting	1	0
Nasal disorder	3	0
Nasal dryness	25	0
Nasal mucosal discolouration	1	0
Nasal odour	6	0
Nasal oedema	4	0
Nasal polyps	1	0
Nasal pruritus	8	0
<b>Neonatal hypoxic conditions</b>		
Dry lung syndrome	1	0
Gasping syndrome	1	0
Infantile apnoea	1	0
<b>Paranasal sinus disorders (excl infections and neoplasms)</b>		
Allergic sinusitis	1	0
Paranasal sinus inflammation	1	0
Sinonasal obstruction	9	0
Sinus congestion	42	0
Sinus disorder	5	0
<b>Parenchymal lung disorders NEC</b>		
Atelectasis	1	0
Combined pulmonary fibrosis and emphysema	1	0
Emphysema	2	0
Interstitial lung disease	8	0
Lung consolidation	1	0

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b> Respiratory disorders cont'd		
Lung infiltration	1	0
Pulmonary alveolar haemorrhage	1	0
Pulmonary cavitation	1	0
Pulmonary fibrosis	4	0
<b>Pharyngeal disorders (excl infections and neoplasms)</b>		
Pharyngeal erythema	6	0
Pharyngeal haemorrhage	2	0
Pharyngeal hypoaesthesia	29	0
Pharyngeal inflammation	4	0
Pharyngeal oedema	12	0
Pharyngeal paraesthesia	48	0
Pharyngeal swelling	184	0
Pharyngeal ulceration	14	0
Tonsillar erythema	4	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	57	0
Tonsillar inflammation	3	0
Tonsillar ulcer	1	0
Tonsillolith	1	0
<b>Pleural infections and inflammations</b>		
Pleurisy	23	0
<b>Pneumothorax and pleural effusions NEC</b>		
Pleural effusion	16	0
Pneumothorax	6	0
Pneumothorax spontaneous	1	0
<b>Pulmonary hypertensions</b>		
Pulmonary hypertension	2	0
<b>Pulmonary oedemas</b>		
Acute respiratory distress syndrome	2	1
Pulmonary congestion	10	0
Pulmonary oedema	17	1
<b>Pulmonary thrombotic and embolic conditions</b>		
Pulmonary embolism	325	19
Pulmonary infarction	3	0
Pulmonary thrombosis	5	1
<b>Respiratory failures (excl neonatal)</b>		
Acute respiratory failure	2	1
Respiratory failure	9	3
<b>Respiratory signs and symptoms NEC</b>		
Allergic respiratory symptom	5	0
Diaphragmalgia	5	0
Nasal flaring	1	0
Painful respiration	6	0
Pleural rub	1	0
Respiratory symptom	12	0
Suffocation feeling	1	0
<b>Respiratory tract disorders NEC</b>		
Aspiration	3	2
Lung disorder	3	0
Pulmonary mass	4	0
Respiratory disorder	8	0
Respiratory tract congestion	2	0
Respiratory tract haemorrhage	1	0

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b> Respiratory disorders cont'd		
Respiratory tract inflammation	1	0
Respiratory tract irritation	5	0
Respiratory tract oedema	3	0
<b>Thoracic musculoskeletal disorders</b>		
Respiratory muscle weakness	2	0
<b>Tracheal disorders (excl infections and neoplasms)</b>		
Tracheal pain	1	0
<b>Upper respiratory tract neoplasms</b>		
Tonsillar cyst	1	0
<b>Upper respiratory tract signs and symptoms</b>		
Aphonia	80	0
Catarrh	16	0
Choking	11	1
Choking sensation	3	0
Dry throat	129	0
Dysphonia	123	0
Increased upper airway secretion	4	0
Increased viscosity of upper respiratory secretion	24	0
Nasal discharge discolouration	2	0
Nasal discomfort	39	0
Nasal obstruction	2	0
Oropharyngeal blistering	9	0
Oropharyngeal discomfort	46	0
Oropharyngeal pain	2099	0
Oropharyngeal plaque	2	0
Paranasal sinus discomfort	32	0
Rhinalgia	10	0
Rhinorrhoea	645	0
Sinus pain	151	0
Sneezing	266	0
Snoring	7	0
Throat clearing	8	0
Throat irritation	181	0
Throat tightness	197	0
Upper airway obstruction	2	0
Upper respiratory tract irritation	1	0
Upper-airway cough syndrome	6	0
Yawning	16	0
<b>Vascular pulmonary disorders NEC</b>		
Acute chest syndrome	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>11903</b>	<b>47</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<i><b>Acnes</b></i>		
Acne	112	0
Acne cystic	11	0
Dermatitis acneiform	8	0
<i><b>Alopecias</b></i>		
Alopecia	138	0
Alopecia areata	17	0
Alopecia totalis	1	0
Androgenetic alopecia	1	0
Madarosis	2	0
<i><b>Angioedemas</b></i>		
Angioedema	150	0
Circumoral swelling	1	0
<i><b>Apocrine and eccrine gland disorders</b></i>		
Anhidrosis	1	0
Cold sweat	534	0
Hidradenitis	2	0
Hyperhidrosis	1536	0
Milia	1	0
Miliaria	67	0
Night sweats	431	0
<i><b>Bullous conditions</b></i>		
Blister	345	0
Blister rupture	1	0
Blood blister	21	0
Dermatitis bullous	10	0
Erythema multiforme	24	0
Fracture blisters	1	0
Pemphigoid	18	0
Pemphigus	5	0
Stevens-Johnson syndrome	4	0
Toxic epidermal necrolysis	2	1
<i><b>Connective tissue disorders</b></i>		
Dermatomyositis	4	0
<i><b>Dermal and epidermal conditions NEC</b></i>		
Acute febrile neutrophilic dermatosis	1	0
Dermatosis	1	0
Dry skin	158	0
Macule	4	0
Neutrophilic dermatosis	1	0
Pain of skin	192	0
Papule	78	0
Pathergy reaction	1	0
Peau d'orange	2	0
Scab	17	0
Scar pain	11	0
Sensitive skin	117	0
Skin burning sensation	164	0
Skin degenerative disorder	1	0
Skin discolouration	85	0
Skin discomfort	3	0
Skin disorder	11	0
Skin fissures	5	0

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Skin indentation	2	0
Skin induration	3	0
Skin lesion	31	0
Skin lesion inflammation	1	0
Skin necrosis	1	0
Skin odour abnormal	14	0
Skin plaque	2	0
Skin reaction	102	0
Skin sensitisation	24	0
Skin swelling	61	0
Skin texture abnormal	1	0
Skin tightness	21	0
Skin warm	219	0
Skin weeping	7	0
Sticky skin	1	0
Target skin lesion	2	0
Transient acantholytic dermatosis	1	0
Yellow skin	15	0
<b><i>Dermatitis and eczema</i></b>		
Dermatitis	83	0
Dermatitis allergic	171	0
Dermatitis atopic	23	0
Dermatitis contact	11	0
Dermatitis diaper	3	0
Dyshidrotic eczema	17	0
Eczema	192	0
Eczema asteatotic	7	0
Eczema infantile	1	0
Eczema nummular	4	0
Eczema weeping	1	0
Intertrigo	1	0
Perioral dermatitis	1	0
Seborrhoeic dermatitis	2	0
Skin irritation	79	0
<b><i>Dermatitis ascribed to specific agent</i></b>		
Drug eruption	26	0
Drug reaction with eosinophilia and systemic symptoms	1	0
Fixed eruption	2	0
Toxic skin eruption	1	0
<b><i>Erythemas</i></b>		
Erythema	1610	0
Palmar erythema	4	0
Red man syndrome	1	0
<b><i>Exfoliative conditions</i></b>		
Dermatitis exfoliative	2	0
Dermatitis exfoliative generalised	4	0
Exfoliative rash	16	0
Keratolysis exfoliativa acquired	2	0
Skin exfoliation	76	0
<b><i>Granulomatous and deep cutaneous inflammatory conditions</i></b>		
Cutaneous sarcoidosis	1	0
Granuloma annulare	2	0
<b><i>Hyperkeratoses</i></b>		

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Hyperkeratosis	1	0
Keratosis pilaris	3	0
Lichenoid keratosis	3	0
<b>Hyperpigmentation disorders</b>		
Argyria	1	0
Chloasma	1	0
Ephelides	1	0
Skin hyperpigmentation	3	0
Solar lentigo	2	0
<b>Hypertrichoses</b>		
Hirsutism	1	0
<b>Hypopigmentation disorders</b>		
Skin depigmentation	4	0
Skin hypopigmentation	1	0
Vitiligo	8	0
<b>Lipodystrophies</b>		
Lipoatrophy	4	0
Lipodystrophy acquired	1	0
<b>Nail and nail bed conditions (excl infections and infestations)</b>		
Nail discolouration	7	0
Nail disorder	3	0
Nail pigmentation	2	0
Nail ridging	1	0
Onychalgia	6	0
Onychoclasia	4	0
Onychomadesis	2	0
Splinter haemorrhages	3	0
<b>Panniculitides</b>		
Erythema nodosum	21	0
<b>Papulosquamous conditions</b>		
Erythema annulare	2	0
Lichen planus	11	0
Lichen sclerosus	7	0
Parapsoriasis	2	0
Pityriasis rosea	74	0
<b>Photosensitivity and photodermatosis conditions</b>		
Photosensitivity reaction	46	0
Polymorphic light eruption	2	0
Solar dermatitis	1	0
<b>Pigmentation changes NEC</b>		
Haemosiderin stain	1	0
Pigmentation disorder	9	0
<b>Pilar disorders NEC</b>		
Hair colour changes	8	0
Hair disorder	1	0
Hair growth abnormal	4	0
Hair texture abnormal	4	0
Piloerection	20	0
Pseudofolliculitis	2	0
<b>Pruritus NEC</b>		
Itching scar	5	0
Pruritus	3831	0
<b>Psoriatic conditions</b>		

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Dermatitis psoriasiform	2	0
Guttate psoriasis	12	0
Nail psoriasis	1	0
Palmoplantar pustulosis	2	0
Psoriasis	116	0
Pustular psoriasis	2	0
<b>Purpura and related conditions</b>		
Henoch-Schonlein purpura	4	0
Petechiae	103	0
Purpura	36	0
<b>Pustular conditions</b>		
Acute generalised exanthematous pustulosis	1	0
<b>Rashes, eruptions and exanthems NEC</b>		
Butterfly rash	3	0
Rash	4085	0
Rash erythematous	880	0
Rash macular	383	0
Rash maculo-papular	47	0
Rash morbilliform	34	0
Rash papular	256	0
Rash pruritic	877	0
Rash vesicular	49	0
Systemic lupus erythematosus rash	6	0
<b>Rosaceas</b>		
Rosacea	22	0
<b>Scaly conditions</b>		
Dandruff	4	0
Pityriasis	16	0
<b>Sebaceous gland disorders</b>		
Seborrhoea	6	0
<b>Skin and subcutaneous conditions NEC</b>		
Cutaneous symptom	4	0
Reactive perforating collagenosis	1	0
Skin mass	14	0
<b>Skin and subcutaneous tissue ulcerations</b>		
Mucocutaneous ulceration	1	0
Scleroderma associated digital ulcer	1	0
Skin erosion	19	0
Skin ulcer	10	0
<b>Skin cysts and polyps</b>		
Dermal cyst	9	0
<b>Skin dystrophies</b>		
Keloid scar	2	0
Skin wrinkling	2	0
<b>Skin haemorrhages</b>		
Haemorrhage subcutaneous	6	0
Skin haemorrhage	10	0
<b>Skin hyperplasias and hypertrophies</b>		
Skin hypertrophy	2	0
<b>Skin hypoplasias and atrophies</b>		
Skin atrophy	1	0
Skin striae	5	0
<b>Skin injuries and mechanical dermatoses</b>		

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Decubitus ulcer	2	0
Needle track marks	1	0
<b>Skin preneoplastic conditions NEC</b>		
Actinic keratosis	1	0
<b>Skin vascular conditions NEC</b>		
Skin oedema	3	0
<b>Skin vasculitides</b>		
Capillaritis	1	0
Cutaneous vasculitis	10	0
Vasculitic rash	16	0
<b>Skin vasomotor conditions</b>		
Livedo reticularis	18	0
<b>Telangiectasia and related conditions</b>		
Telangiectasia	1	0
<b>Urticarias</b>		
Chronic spontaneous urticaria	3	0
Cold urticaria	2	0
Idiopathic urticaria	1	0
Mechanical urticaria	5	0
Solar urticaria	2	0
Urticaria	1294	0
Urticaria cholinergic	1	0
Urticaria chronic	10	0
Urticaria contact	1	0
Urticaria papular	3	0
Urticaria thermal	4	0
Urticarial vasculitis	3	0
<b>Skin disorders SOC TOTAL</b>	<b>19681</b>	<b>1</b>



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Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i><b>Age related issues</b></i>		
Infant	1	0
Menopause	19	0
Postmenopause	3	0
<i><b>Criminal activity</b></i>		
Verbal abuse	1	0
<i><b>Dependents</b></i>		
Sick relative	4	0
<i><b>Disability issues</b></i>		
Bedridden	17	0
Breast prosthesis user	3	0
Disability	1	0
Hearing disability	1	0
Housebound	1	0
Immobile	11	0
Impaired driving ability	2	0
Impaired work ability	7	0
Loss of personal independence in daily activities	27	0
Physical disability	3	0
Sight disability	8	0
Sitting disability	1	0
Walking disability	1	0
<i><b>Economic circumstances</b></i>		
High income	1	0
Low income	1	0
<i><b>Employment issues</b></i>		
Retirement	4	0
Stress at work	1	0
<i><b>Family and partner issues</b></i>		
Bed sharing	1	0
<i><b>Non-occupational and unspecified environmental problems</b></i>		
Flooding	1	0
Water pollution	2	0
<i><b>Pregnancy related circumstances</b></i>		
Breast feeding	11	0
Multigravida	1	0
<i><b>Social issues NEC</b></i>		
Hair dye user	2	0
<i><b>Tobacco use</b></i>		
Ex-tobacco user	1	0
Non-tobacco user	4	0
Tobacco user	1	0
<b>Social circumstances SOC TOTAL</b>	<b>142</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Anaesthesia and allied procedures</i>		
Local anaesthesia	1	0
Nerve block	4	0
<i>Antiinfective therapies</i>		
COVID-19 treatment	3	0
<i>Arterial therapeutic procedures (excl aortic)</i>		
Splenic artery embolisation	1	0
<i>Blood and blood product treatment</i>		
Transfusion	1	0
<i>Breast therapeutic procedures NEC</i>		
Axillary lymphadenectomy	2	0
Mammoplasty	1	0
<i>Bronchial and pulmonary therapeutic procedures</i>		
Airway secretion clearance therapy	1	0
<i>Cardiac therapeutic procedures NEC</i>		
Cardiac operation	1	0
<i>Contraceptive methods female</i>		
Contraception	1	0
Contraceptive implant	2	0
Oral contraception	1	0
<i>Contraceptive methods male</i>		
Condom	1	0
<i>Dietary and nutritional therapies</i>		
Medical diet	6	0
Nothing by mouth order	5	0
Wheat-free diet	1	0
<i>External ear therapeutic procedures</i>		
Ear irrigation	1	0
<i>Fertility and fertilisation interventions female</i>		
Endometrial scratching	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Intestinal anastomosis	1	0
Prophylaxis of nausea and vomiting	11	0
<i>Gynaecological therapeutic procedures NEC</i>		
Menstrual cycle management	5	0
<i>Haematological therapeutic procedures NEC</i>		
Anticoagulant therapy	1	0
<i>Head, neck and oral cavity therapeutic procedures NEC</i>		
Neck lift	1	0
<i>Hernia repairs</i>		
Hernia repair	1	0
<i>Hormonal therapeutic procedures NEC</i>		
Hormone replacement therapy	1	0
Hormone therapy	6	0
<i>Immunisations</i>		
COVID-19 immunisation	75	1
Immunisation	27	0
<i>Joint therapeutic procedures</i>		
Joint surgery	1	0
Knee arthroplasty	1	0
<i>Large intestine therapeutic procedures</i>		
Appendectomy	2	0
<i>Limb therapeutic procedures</i>		

## Case Series Drug Analysis Print

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Report Run Date: 29-Jul-2021  
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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
Surgical & medical procedures cont'd		
Limb immobilisation	7	0
Limb operation	5	0
<b>Lymphoid tissue therapeutic procedures</b>		
Lymphadenectomy	1	0
Splenectomy	1	0
<b>Mastectomies</b>		
Breast conserving surgery	3	0
<b>Nail therapeutic procedures</b>		
Nail operation	2	0
<b>Nervous system therapeutic procedures NEC</b>		
Multiple sclerosis relapse prophylaxis	2	0
<b>Orbit and globe therapeutic procedures</b>		
Strabismus correction	1	0
<b>Peripheral nerve therapeutic procedures</b>		
Peripheral nerve neurostimulation	1	0
<b>Phototherapies</b>		
UV light therapy	1	0
<b>Prophylactic procedures NEC</b>		
Anaphylaxis prophylaxis	2	0
Immune tolerance induction	1	0
Prophylaxis against transplant rejection	1	0
Reproductive system disorder prophylaxis	1	0
<b>Psychiatric therapies</b>		
Electroconvulsive therapy	1	0
<b>Renal therapeutic procedures</b>		
Dialysis	1	0
<b>Respiratory tract therapeutic procedures NEC</b>		
Asthma prophylaxis	2	0
<b>Retinal therapeutic procedures</b>		
Retinopexy	1	0
<b>Skin and subcutaneous tissue therapeutic procedures NEC</b>		
Dermal filler injection	3	0
<b>Small intestine therapeutic procedures</b>		
Ileostomy	1	0
<b>Therapeutic bladder catheterisation</b>		
Bladder catheterisation	1	0
<b>Therapeutic procedures NEC</b>		
Abscess drainage	1	0
Anaphylaxis treatment	4	0
Bed rest	2	0
Fatigue management	1	0
Hospitalisation	9	0
Injection	26	0
Interchange of vaccine products	3	0
Localised alternating hot and cold therapy	1	0
Magnetic therapy	1	0
Mass excision	2	0
Medication dilution	2	0
Product used for unknown indication	2	0
Therapeutic procedure	1	0
Therapy change	1	0
<b>Tracheal therapeutic procedures</b>		
Tracheostomy	1	0

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<b>Surgical &amp; medical procedures</b>		
<i>Surgical &amp; medical procedures cont'd</i>		
<b><i>Uterine therapeutic procedures</i></b>		
Endometrial ablation	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>264</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	10	0
Hypertensive urgency	1	0
Malignant hypertension	3	0
<i><b>Aneurysms and dissections non-site specific</b></i>		
Aneurysm	1	0
Artery dissection	1	0
<i><b>Aortic aneurysms and dissections</b></i>		
Acute aortic syndrome	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	2	0
<i><b>Arterial infections and inflammations</b></i>		
Arteritis	1	0
Giant cell arteritis	10	0
<i><b>Blood pressure disorders NEC</b></i>		
Blood pressure fluctuation	10	0
Labile blood pressure	3	0
<i><b>Bruising, ecchymosis and purpura</b></i>		
Achenbach syndrome	3	0
<i><b>Circulatory collapse and shock</b></i>		
CT hypotension complex	2	0
Circulatory collapse	52	0
Hypoperfusion	1	0
Neurogenic shock	21	0
Peripheral circulatory failure	5	0
Shock	14	0
<i><b>Haemorrhages NEC</b></i>		
Bloody discharge	13	0
Haematoma	35	0
Haemorrhage	689	2
Internal haemorrhage	6	0
Venous haemorrhage	1	0
<i><b>Lymphangiopathies</b></i>		
Lymphangiopathy	1	0
Lymphocele	4	0
<i><b>Lymphoedemas</b></i>		
Lymphoedema	142	0
<i><b>Non-site specific embolism and thrombosis</b></i>		
Arterial thrombosis	3	0
Embolism	60	0
Embolism venous	5	0
Microembolism	1	0
Thrombosis	307	6
Venous thrombosis	4	0
<i><b>Non-site specific necrosis and vascular insufficiency NEC</b></i>		
Arterial occlusive disease	2	0
Arteriosclerosis	1	0
Haemorrhagic infarction	1	0
Infarction	3	0
Ischaemia	7	0

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Reaction Name	Total	Fatal
<b>Vascular disorders</b> Vascular disorders cont'd		
Vasospasm	1	0
<b>Non-site specific vascular disorders NEC</b>		
Capillary disorder	1	0
Superficial vein prominence	1	0
Vascular pain	16	0
Vasodilatation	24	0
Vein discolouration	5	0
Vein disorder	6	0
Vein rupture	4	0
<b>Peripheral embolism and thrombosis</b>		
Axillary vein thrombosis	1	0
Blue toe syndrome	22	0
Deep vein thrombosis	204	1
Femoral artery embolism	1	0
Jugular vein thrombosis	3	0
Pelvic venous thrombosis	4	0
Peripheral embolism	1	0
Subclavian vein thrombosis	3	0
Thrombophlebitis	16	0
Thrombophlebitis superficial	10	0
<b>Peripheral vascular disorders NEC</b>		
Cyanosis	30	0
Erythromelalgia	1	0
Flushing	343	0
Hot flush	825	0
Peripheral vascular disorder	1	0
<b>Peripheral vasoconstriction, necrosis and vascular insufficiency</b>		
Extremity necrosis	2	0
Intermittent claudication	1	0
Ischaemic limb pain	1	0
Peripheral arterial occlusive disease	2	0
Peripheral artery occlusion	1	0
Peripheral coldness	234	0
Peripheral ischaemia	12	0
Poor peripheral circulation	11	0
Raynaud's phenomenon	46	0
Vasoconstriction	2	0
<b>Phlebitis NEC</b>		
Phlebitis	23	0
Phlebitis superficial	5	0
<b>Site specific vascular disorders NEC</b>		
Inferior vena cava dilatation	1	0
Pallor	245	0
<b>Varicose veins NEC</b>		
Spider vein	3	0
Varicophlebitis	4	0
Varicose vein	16	0
<b>Vascular hypertensive disorders NEC</b>		
Diastolic hypertension	2	0
Essential hypertension	3	0
Hypertension	411	1
Labile hypertension	1	0
Orthostatic hypertension	1	0

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<b>Vascular disorders</b> Vascular disorders cont'd		
Secondary hypertension	1	0
Systolic hypertension	4	0
<b>Vascular hypotensive disorders</b>		
Hypotension	290	0
Orthostatic hypotension	23	0
<b>Vasculitides NEC</b>		
Behcet's syndrome	4	0
Diffuse vasculitis	1	0
Granulomatosis with polyangiitis	1	0
MAGIC syndrome	1	0
Vasculitis	40	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>4350</b>	<b>11</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>275820</b>	<b>478</b>
<b>TOTAL REPORTS</b>	<b>98432</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>478</b>