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

All UK spontaneous reports received between 9/12/20 and 14/07/21 for mRNA Pfizer/BioNTech vaccine analysis print.

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

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968	MedDRA Version: MedDRA 24.0	
Reaction Name	Total	Fatal
Blood disorders		
Anaemia deficiencies		
Anaemia folate deficiency		
Anaemia vitamin B12 deficiency		2 0
Deficiency anaemia		1 0
Iron deficiency anaemia		5 0
Anaemias NEC		
Anaemia	67	7 0
Anaemia macrocytic		1 0
Anaemia megaloblastic		1 0
Autoimmune anaemia		2 0
Microcytic anaemia		1 0
Anaemias haemolytic NEC		
Haemolytic anaemia	ţ	5 0
Anaemias haemolytic immune		
Autoimmune haemolytic anaemia	8	3 1
Anaemias haemolytic mechanical factor		·
Microangiopathic haemolytic anaemia		1 0
Bleeding tendencies		
Haemorrhagic diathesis		1 0
Increased tendency to bruise	20	
Spontaneous haematoma		2 0
Coagulation factor deficiencies		
Acquired haemophilia		2 0
Coagulopathies	· · · · · · · · · · · · · · · · · · ·	
Abnormal clotting factor		3 0
Antiphospholipid syndrome		5 0 9 1
Coagulopathy		
Disseminated intravascular coagulation		
Hypercoagulation		3 0
Thrombotic microangiopathy	4	2 0
Eosinophilic disorders	1.	
Eosinophilia	1.	1 0
Haematological disorders		
Blood disorder		
Mast cell activation syndrome	2	4 0
Methaemoglobinaemia		1 0
Haemolyses NEC		
Haemolysis		Ĭ
Intravascular haemolysis		1 0
Leukocytoses NEC		
Leukocytosis		1 0
Lymphocytosis		5 0
Neutrophilia		5 0
Leukopenias NEC		
Leukopenia		
Lymphopenia		3 0
Lymphatic system disorders NEC		
Abdominal lymphadenopathy		2 0
Hilar lymphadenopathy		2 0
Lymph node pain	1008	3 0
Lymphadenitis	100	
Lymphadenopathy	6719	
Lymphatic disorder		

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 24.0 Reaction Name MedDRA Version: MedDRA 24.0	Total	Fatal
Blood disorders Blood disorders cont'd		
Necrotic lymphadenopathy	2	0
Pseudolymphoma	6	0
Retroperitoneal lymphadenopathy	1	0
Marrow depression and hypoplastic anaemias		
Aplasia pure red cell	2	0
Hypoplastic anaemia	1	0
Myelosuppression	1	0
Pancytopenia	6	0
Neutropenias		
Autoimmune neutropenia	2	0
Neutropenia	32	0
Platelet disorders NEC		
Platelet anisocytosis	1	0
Purpuras (excl thrombocytopenic)		
Purpura non-thrombocytopenic	1	0
Red blood cell abnormal findings NEC		
Polychromasia	2	0
Red blood cell abnormality	3	0
Spleen disorders		
Spleen atrophy	1	0
Splenic infarction	1	0
Splenic vein thrombosis	1	0
Splenomegaly	9	0
Thrombocytopenias		
Immune thrombocytopenia	69	0
Thrombocytopenia	153	1
Thrombocytopenic purpura	4	0
Thrombotic thrombocytopenic purpura	5	0
Thrombocytoses		
Thrombocytosis	4	0
Blood disorders SOC TOTAL	8332	3

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968	MedDRA Version: MedDRA 24.0	Tatal	E a f a f
Reaction Name		Total	Fatal
Cardiac disorders			
Cardiac conduction disorders		_	
Atrioventricular block		7	1
Atrioventricular block complete		1	0
Atrioventricular block first degree		1	0
Atrioventricular block second degree		1	0
Bundle branch block		2	0
Bundle branch block right		1	0
Cardiac disorders NEC		_	-
Acute cardiac event		3	0
Cardiac disorder		31	0
Cardiac dysfunction		1	0
Cardiovascular deconditioning		1	0
Cardiovascular disorder		4	0
Intracardiac thrombus		2	0
Cardiac hypertensive complications			
Hypertensive heart disease		1	0
Cardiac infections and inflammations NEC			
Carditis		1	0
Cardiac signs and symptoms NEC			
Cardiac discomfort		7	0
Cardiovascular symptom		1	0
Palpitations		1775	0
Cardiac valve disorders NEC			
Cardiac valve disease		1	0
Heart valve incompetence		1	0
Cardiomyopathies			
Cardiomyopathy		3	0
Congestive cardiomyopathy		4	0
Stress cardiomyopathy		2	0
Coronary artery disorders NEC			
Coronary artery disease		4	2
Coronary artery occlusion		1	0
Coronary artery thrombosis		1	0
Heart failures NEC			
Cardiac failure		45	6
Cardiac failure acute		2	0
Cardiac failure chronic		1	0
Cardiac failure congestive		3	1
Cardiogenic shock		4	1
Cardiopulmonary failure		1	1
Ischaemic coronary artery disorders			
Acute coronary syndrome		3	0
Acute myocardial infarction		17	1
Angina pectoris		96	0
Angina unstable		2	0
Arteriospasm coronary		1	0
Microvascular coronary artery disease		2	C
Myocardial infarction		140	25
Myocardial ischaemia		6	2
Left ventricular failures			
Acute left ventricular failure		1	1
Left ventricular failure		5	2
Mitral valvular disorders			

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDR	-	
Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Mitral valve incompetence	3	0
Mitral valve prolapse	1	0
Myocardial disorders NEC		
Cardiac amyloidosis	1	0
Cardiomegaly	9	1
Left atrial dilatation	1	0
Left ventricular dysfunction	4	0
Left ventricular enlargement	1	0
Left ventricular hypertrophy	1	0
Myocardial fibrosis	1	0
Myocardial haemorrhage	1	0
Myocardial oedema	3	0
Myocardial rupture	1	0
Right ventricular enlargement	1	0
Ventricular hypertrophy	2	0
Noninfectious myocarditis		
Myocarditis	112	1
Noninfectious pericarditis		
Pericarditis	103	1
Pericardial disorders NEC		
Pericardial effusion	12	0
Pericardial haemorrhage	3	3
Pericardial rub	1	0
Rate and rhythm disorders NEC		
Arrhythmia	77	0
Bradycardia	45	0
Cardiac flutter	188	0
Extrasystoles	87	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	10	0
Tachyarrhythmia	1	0
Tachycardia	557	0
Right ventricular failures		
Cor pulmonale	1	0
Supraventricular arrhythmias		
Arrhythmia supraventricular	8	0
Atrial fibrillation	134	0
Atrial flutter	11	0
Atrial tachycardia	4	0
Nodal arrhythmia	1	0
Sinus arrest	1	0
Sinus arrhythmia	1	0
Sinus bradycardia	5	0
Sinus tachycardia	36	0
Supraventricular tachycardia	27	0
Tricuspid valvular disorders		
Tricuspid valve incompetence	1	0
Ventricular arrhythmias and cardiac arrest		
Cardiac arrest	80	31
Cardio-respiratory arrest	1	1
Pulseless electrical activity	3	0
Ventricular arrhythmia	4	0
Ventricular extrasystoles	12	0

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

Report Run Date: 15-Jul-2021	
Earliest Reaction Date: 13-Apr-1968	

Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Ventricular fibrillation	6	1
Ventricular tachycardia	10	0
Cardiac disorders SOC TOTAL	3759	82

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

	dDRA Version: MedDRA 24.0	
Reaction Name	<u>Total</u>	Fatal
Congenital disorders		
Cardiac disorders congenital NEC		
Heart disease congenital	10	0 0
Cardiac septal defects congenital		
Hypertrophic cardiomyopathy	1	0
Central nervous system disorders congenital NE	EC	
Encephalocele	1	0
Spina bifida	1	0
Cerebellar disorders congenital		Ů
Arnold-Chiari malformation	1	0
Hereditary ataxia	1	0
Cerebral disorders congenital		Ŭ
Cerebral palsy	2	0
Chemically-induced congenital syndromes	2	. 0
Foetal warfarin syndrome	1	0
Coagulation disorders congenital		0
	1	0
Haemophilia		0
Congenital disorders NEC		
Foetal malformation		0
Young's syndrome	1	0
Connective tissue disorders congenital		
Ehlers-Danlos syndrome	2	2 0
External ear disorders congenital		
Anotia	1	0
Gastrointestinal tract disorders congenital NEC		
Gastroschisis	1	0
Great vessel disorders congenital		
Transposition of the great vessels	1	0
Haematological disorders congenital NEC		
Amegakaryocytic thrombocytopenia	1	0
Neonatal alloimmune thrombocytopenia	1	0
Haemoglobinopathies congenital		
Congenital methaemoglobinaemia	1	0
Lymphatic system disorders congenital		
Cystic lymphangioma	2	2 0
Male reproductive tract disorders congenital		
Cryptorchism	1	0
Micropenis	2	2 0
Musculoskeletal and connective tissue disorders	s of limbs congenital	
Developmental hip dysplasia	1	0
Musculoskeletal disorders congenital NEC		
Congenital multiplex arthrogryposis	1	0
Neurological disorders congenital NEC		
Familial hemiplegic migraine	2	2 0
Familial periodic paralysis	1	0
Moebius II syndrome	1	0
Palate disorders congenital		
Cleft lip and palate	1	0
Peripheral nervous system disorders congenital	NEC	
Hereditary neuropathy with liability to pressure		0
Pulmonary and bronchial disorders congenital		
Congenital cystic lung	1	0
Retinal disorders congenital		
Retinitis pigmentosa	1	0
		0

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

Report Run Date: 15-Jul-2021	Data Lock Date: 14-Jul-2021 18:30	:32	
Earliest Reaction Date: 13-Apr-1968	MedDRA Version: MedDRA 24.0		
Reaction Name		Total	Fatal
Congenital disordersCongenital disorders cont'd			
Tongue disorders congenital			
Ankyloglossia congenital		1	0
Congenital disorders SOC TOTAL		45	0

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Reaction Name	MedDRA Version: MedDRA 24.0	Total	Fatal
Ear disorders			
Ear disorders NEC			
Ear canal erythema		1	0
Ear congestion		19	0
Ear discomfort		60	C
Ear disorder		12	C
Ear haemorrhage		7	0
Ear pain		635	0
Ear pruritus		6	0
Ear swelling		23	0
Otorrhoea		3	0
Eustachian tube disorders			
Eustachian tube disorder		2	0
Eustachian tube dysfunction		7	0
Eustachian tube obstruction		2	0
External ear disorders NEC			
Auricular swelling		1	0
Excessive cerumen production		4	0
External ear pain		2	0
Red ear syndrome		2	0
External ear infections and inflammations			
External ear inflammation		2	0
Hearing disorders NEC			
Auditory disorder		5	0
Diplacusis		1	0
Hearing losses			
Conductive deafness		1	0
Deafness		160	0
Deafness bilateral		6	0
Deafness neurosensory		12	0
Deafness transitory		3	0
Deafness unilateral		24	0
Hypoacusis		121	0
Sudden hearing loss		28	0
Hyperacusia			
Hyperacusis		31	0
Misophonia		3	0
Inner ear disorders NEC			
Acute vestibular syndrome		1	0
Inner ear disorder		8	0
Meniere's disease		8	0
Vestibular disorder		8	C
Inner ear infections and inflammations			
Inner ear inflammation		4	0
Inner ear signs and symptoms			
Motion sickness		35	0
Tinnitus		1257	C
Vertigo		901	C
Vertigo labyrinthine		9	C
Vertigo positional		58	C
Mastoid disorders			
Mastoid effusion		1	0
Middle ear disorders NEC		,	Ŭ
Middle ear disorder		3	C

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Total	Fatal
1	0
1	0
3478	0
	Total

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 24.0	Total	Fatal
Endocrine disorders		
Acute and chronic thyroiditis		
Autoimmune thyroiditis	1	0
Thyroiditis	9	0
Thyroiditis acute	1	0
Thyroiditis subacute	2	0
Adrenal cortical hypofunctions		
Addison's disease	1	0
Adrenocortical insufficiency acute	9	0
Adrenal gland disorders NEC		
Adrenal haemorrhage	2	0
Anterior pituitary hyperfunction		
Pituitary-dependent Cushing's syndrome	1	0
Anterior pituitary hypofunction		
Hypopituitarism	1	0
Endocrine abnormalities of puberty		
Delayed menarche	3	0
Premature menarche	12	0
Female gonadal function disorders		
Anovulatory cycle	21	0
Ovulation delayed	14	0
Thyroid disorders NEC		
Autoimmune thyroid disorder	1	0
Goitre	10	0
Thyroid disorder	6	0
Thyroid mass	1	0
Thyroid pain	3	0
Thyroid hyperfunction disorders		
Basedow's disease	2	0
Hyperthyroidism	18	0
Thyrotoxic crisis	2	0
Thyroid hypofunction disorders		
Autoimmune hypothyroidism	1	0
Hypothyroidism	19	0
Endocrine disorders SOC TOTAL	140	0

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 24.0		
Reaction Name	<u>Total</u>	<u>Fatal</u>
Eye disorders		
Amblyopic vision impairment		
Amblyopia	5	0
Cataract conditions		
Cataract	9	0
Choroid and vitreous haemorrhages and vascular disorders		
Choroidal haemorrhage	1	0
Choroidal neovascularisation	1	0
Vitreous haemorrhage	3	0
Choroid and vitreous structural change, deposit and degeneration		
Chorioretinopathy	2	0
Vitreous detachment	15	
Vitreous floaters	50	
Colour blindness (incl acquired)	00	0
Dyschromatopsia	3	0
Conjunctival and corneal bleeding and vascular disorders		0
Conjunctival haemorrhage	28	0
Conjunctival infections, irritations and inflammations	20	0
	2	0
Conjunctival hyperaemia		-
Conjunctival irritation	1	0
Conjunctival oedema	3	0
Corneal infections, oedemas and inflammations	-	
Keratitis	5	0
Ulcerative keratitis	4	0
Eyelid movement disorders		_
Blepharospasm	88	0
Excessive eye blinking	2	0
Eyelid function disorder	3	0
Eyelid myokymia	3	0
Eyelid ptosis	35	0
Glaucomas (excl congenital)		
Angle closure glaucoma	2	0
Glaucoma	5	0
Iris and ciliary body structural change, deposit and degeneration		
Eye colour change	2	0
Iris and uveal tract infections, irritations and inflammations		
Autoimmune uveitis	1	0
Iridocyclitis	8	0
Iritis	4	0
Uveitis	25	0
Lacrimation disorders		
Dry eye	97	0
Lacrimation increased	90	0
Lid bleeding and vascular disorders		
Eyelid bleeding	1	0
Lid, lash and lacrimal infections, irritations and inflammations		-
Blepharitis	7	0
Chalazion	. 7	0
Eczema eyelids	3	
Erythema of eyelid	1	
Eyelid cyst	4	C
Eyelid irritation	2	C
Eyelid margin crusting	3	
Eyelid oedema	3	0

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Eyelid rash	12	2 0
Swelling of eyelid	91	
Lid, lash and lacrimal structural disorders		
Dermatochalasis		ı o
Eyelash changes		i o
Eyelid exfoliation		
Eyelid skin dryness		
Floppy eyelid syndrome	2	
Growth of eyelashes		
Lagophthalmos		
Ocular bleeding and vascular disorders NEC		
Eye haematoma	4	4 O
Eye haemorrhage	20	
Ocular vascular disorder	20	
Ophthalmic vein thrombosis		
Ocular disorders NEC		
Dark circles under eyes	6	5 O
	19	
Eye disorder Eye oedema		
	694	
Eye pain	334	
Eye swelling		
Eye symptom		-
Eye ulcer		
Eyelid disorder	10	
Eyelid pain Eyelids pruritus		
Ocular discomfort	19	
Periorbital oedema	15	
Periorbital pain Periorbital swelling	87	
Retinal disorder	01	
Vitreous disorder		
Ocular infections, inflammations and associa	tod manifactations	
Eye allergy		7 0
Eye discharge	16	
	18	
Eye inflammation Eye irritation	74	
	177	
Eye pruritus		
Limbal swelling	147	
Ocular hyperaemia	147	7 0
Ocular nerve and muscle disorders		
Binocular eye movement disorder		
Extraocular muscle disorder		
Extraocular muscle paresis		
Eye movement disorder	22	
Ocular myasthenia		
Ophthalmoplegia	3	
Strabismus		۹ o
Ocular sensation disorders		
Abnormal sensation in eye	10	
Asthenopia	107	
Eye paraesthesia	1	
Foreign body sensation in eyes	16	6 C

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 24.0		
Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Hypoaesthesia eye	11	0
Photophobia	269	0
Optic disc abnormalities NEC		
Papilloedema	4	0
Optic nerve bleeding and vascular disorders		
Optic disc haemorrhage	1	0
Optic ischaemic neuropathy	2	0
Orbital infections, inflammations and irritations		
Parophthalmia	1	0
Orbital structural change, deposit and degeneration		
Orbital oedema	2	0
Pupil disorders		
Miosis	2	0
Mydriasis	16	0
Pupil fixed	2	0
Pupils unequal	7	0
Refractive and accommodative disorders		
Altered visual depth perception	1	0
Astigmatism	1	0
Муоріа	1	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Retinal artery occlusion	6	0
Retinal artery thrombosis	1	0
Retinal haemorrhage	4	0
Retinal vein occlusion	21	0
Retinal vein thrombosis	2	0
Retinal structural change, deposit and degeneration		
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
Retinal, choroid and vitreous infections and inflammations		
Cystoid macular oedema	1	0
Macular oedema	2	0
Retinal vasculitis	3	0
Retinopathies NEC		-
Acute macular outer retinopathy	1	0
Retinal exudates	2	0
Retinopathy	1	0
Scleral infections, irritations and inflammations		
Episcleritis	7	0
Scleritis	2	0
Scleral structural change, deposit and degeneration		
Scleral discolouration	2	0
Visual colour distortions		
Chloropsia	3	0
Cyanopsia	1	0
Erythropsia	2	0
Xanthopsia	1	0

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Visual disorders NEC		
Diplopia	113	0
Glare	1	0
Halo vision	6	0
Metamorphopsia	14	0
Oscillopsia	2	0
Photopsia	83	0
Scintillating scotoma	3	0
Vision blurred	768	0
Visual brightness	3	0
Visual snow syndrome	2	0
Visual field disorders		
Visual field defect	12	0
Visual impairment and blindness (excl colour blindness)		
Amaurosis fugax	2	0
Blindness	76	0
Blindness transient	7	0
Blindness unilateral	9	0
Central vision loss	2	0
Sudden visual loss	3	0
Visual acuity reduced	14	0
Visual acuity reduced transiently	1	0
Visual impairment	209	0
Visual pathway disorders		
Optic nerve disorder	1	0
Eve disorders SOC TOTAL	4227	0

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968	MedDRA Version: MedDRA 24.0	
Reaction Name	Total	Fatal
Gastrointestinal disorders		
Abdominal findings abnormal		
Abdominal mass	1	0
Gastrointestinal sounds abnormal	14	0
Abdominal hernias NEC		
Abdominal hernia	1	0
Abdominal wall conditions NEC		
Abdominal wall haematoma	1	0
Acute and chronic pancreatitis		
Obstructive pancreatitis	1	0
Pancreatitis	8	0
Pancreatitis acute	7	0
Pancreatitis necrotising	1	0
Anal and rectal disorders NEC		
Anal fissure	1	0
Anal sphincter atony	1	0
Anal and rectal pains		
Proctalgia	8	0
Anal and rectal signs and symptoms		
Anal hypoaesthesia	1	0
Anal spasm	1	0
Anorectal discomfort	3	0
Anorectal swelling	1	0
Rectal discharge	1	0
Rectal tenesmus	1	0
Benign oral cavity neoplasms		
Mouth cyst	4	0
Tongue cyst	4	0
Colitis (excl infective)		
Autoimmune colitis	1	0
Colitis	30	1
Colitis ischaemic	1	0
Colitis microscopic	1	0
Colitis ulcerative	51	0
Crohn's disease	26	0
Eosinophilic colitis	1	0
Inflammatory bowel disease	2	0
Dental and periodontal infections and inflam	mations	
Dental caries	1	0
Dental disorders NEC		
Teeth brittle	1	0
Teething	4	0
Tooth disorder	2	0
Dental pain and sensation disorders		
Dental discomfort	5	0
Dental paraesthesia	10	0
Hyperaesthesia teeth	25	0
Toothache	98	0
Dental surface disorders		
Tooth discolouration	4	0
Diaphragmatic hernias		
Hiatus hernia	4	0
Diarrhoea (excl infective)		
Diarrhoea	3583	2

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Reaction Name	Total	Fatal
Gastrointestinal disorders ointestinal disorders of		
Diarrhoea haemorrhagic	17	' C
Diverticula		
Diverticulum	4	. C
Diverticulum intestinal	1	C
Duodenal and small intestinal stenosis and	obstruction	
Small intestinal obstruction	1	C
Duodenal ulcers and perforation		
Duodenal ulcer haemorrhage	1	C
Duodenal ulcer perforation	3	S C
Dyspeptic signs and symptoms		
Dyspepsia	257	
Epigastric discomfort	12	
Eructation	32	2 C
Faecal abnormalities NEC		
Abnormal faeces	12	2 C
Faecaloma	2	2 0
Faeces discoloured	34	C
Faeces hard	1	0
Faeces pale	3	
Faeces soft	10	
Mucous stools	5	
Flatulence, bloating and distension		
Abdominal distension	292	2 C
Aerophagia	3	S C
Flatulence	124	L C
Gastric and oesophageal haemorrhages		
Gastric haemorrhage	5	i 1
Mallory-Weiss syndrome	1	0
Oesophageal varices haemorrhage	1	C
Gastric ulcers and perforation		
Gastric ulcer	6	S C
Gastritis (excl infective)		
Chronic gastritis	2	2 C
Gastritis	32	2 C
Reflux gastritis	4	L C
Gastrointestinal and abdominal pains (excl	oral and throat)	
Abdominal migraine	2	2 C
Abdominal pain	907	
Abdominal pain lower	73	s c
Abdominal pain upper	1469	
Abdominal rigidity	14	L C
Abdominal tenderness	8	
Gastrointestinal pain	87	
Oesophageal pain	4	- C
Gastrointestinal atonic and hypomotility dis	orders NEC	
Constipation	168	
Duodenogastric reflux	3	
Gastric dilatation	6	
Gastrooesophageal reflux disease	79	
Impaired gastric emptying	5	
Infrequent bowel movements	2	
Intestinal pseudo-obstruction	2	
Gastrointestinal disorders NEC		

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 24.0		
Reaction Name	Total	Fatal
Gastrointestinal disorders cont'd		
Food poisoning	2	0
Functional gastrointestinal disorder	6	0
Gastric disorder	5	0
Gastrointestinal disorder	8	0
Stomach mass	3	0
Gastrointestinal dyskinetic disorders		
Bowel movement irregularity	1	0
Change of bowel habit	3	0
Dyschezia	2	0
Gastrointestinal motility disorder	1	0
Oesophageal achalasia	1	0
Gastrointestinal fistulae		
Diverticular fistula	1	0
Gastrointestinal inflammatory disorders NEC		-
Duodenitis	1	0
Enteritis	4	0
Epiploic appendagitis	2	0
Gastrointestinal inflammation	2	0
Intestinal angioedema	2	0
Gastrointestinal mucosal dystrophies and secretion disorders	_	, in the second s
Hyperchlorhydria	4	0
Gastrointestinal signs and symptoms NEC		Ŭ
Abdominal discomfort	416	0
Abdominal symptom	1	0
Acute abdomen	4	0
Anal incontinence	14	0
Breath odour	15	0
Dysphagia	139	
Odynophagia	22	0
Gastrointestinal spastic and hypermotility disorders		U
Cardiospasm	1	0
Defaecation urgency	7	0
Frequent bowel movements	20	0
Irritable bowel syndrome	53	0
Oesophageal spasm	3	0
Pylorospasm	1	0
Gastrointestinal stenosis and obstruction NEC		Ŭ
	2	0
Gastrointestinal vascular malformations	2	U
Gastric antral vascular ectasia	5	0
Gastrointestinal vascular occlusion and infarction	Ŭ	Ŭ
Intestinal ischaemia	5	2
Mesenteric vein thrombosis	4	0
Omental infarction	1	0
Thrombosis mesenteric vessel	1	0
Visceral venous thrombosis	1	0
Gingival disorders, signs and symptoms NEC		0
Gingival blister	11	0
Gingival bister Gingival discomfort	2	0
Gingival disorder	3	0
Gingival disorder Gingival erythema	2	0
Gingival erythema		0
	76	0
Gingival pain	76	0

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 24.0 Reaction Name	Total	Fatal
Gastrointestinal disorders cont'd		
Gingival pruritus	1	0
Gingival swelling	24	0
Gingival ulceration	1	C
Gingivitis ulcerative	1	0
Noninfective gingivitis	4	C
Gingival haemorrhages		
Gingival bleeding	43	C
Haemorrhoids and gastrointestinal varices (excl oesophageal)		
Gastric varices	1	C
Haemorrhoids	20	0
Haemorrhoids thrombosed	1	C
Intestinal haemorrhages		
Anal haemorrhage	11	0
Intestinal haemorrhage	1	0
Rectal haemorrhage	45	0
Small intestinal haemorrhage	6	0
Intestinal ulcers and perforation NEC		
Intestinal perforation	4	2
Large intestine perforation	1	0
Malabsorption syndromes		
Bile acid malabsorption	1	0
Coeliac disease	8	0
Steatorrhoea	4	0
Nausea and vomiting symptoms		
Discoloured vomit	10	0
Infantile vomiting	4	0
Nausea	9584	1
Regurgitation	1	0
Retching	71	0
Vomiting	2785	1
Vomiting projectile	39	0
Non-mechanical ileus		
lleus paralytic	1	0
Non-site specific gastrointestinal haemorrhages		
Gastrointestinal haemorrhage	11	0
Haematemesis	25	2
Haematochezia	34	0
Melaena	8	0
Upper gastrointestinal haemorrhage	2	0
Oesophageal stenosis and obstruction		
Oesophageal stenosis	2	C
Oesophagitis (excl infective)		
Eosinophilic oesophagitis	1	C
Oesophagitis	2	C
Oral dryness and saliva altered		
Aptyalism	2	(
Dry mouth	367	C
Lip dry	30	(
Saliva altered	4	(
Salivary hypersecretion	36	C
Oral soft tissue disorders NEC		
Angina bullosa haemorrhagica	1	C
Chapped lips	15	C

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

	DRA Version: MedDRA 24.0	
Reaction Name	Total	Fatal
Gastrointestinal disorders ointestinal disorders cont'd		-
Cheilitis	19	
Enlarged uvula	10	
Lip blister	18	
Lip disorder	4	
Oral disorder	7	0
Oral lichen planus	5	
Oral mucosal hypertrophy	1	0
Oral papule	1	0
Uvulitis	2	0
Oral soft tissue haemorrhages		-
Mouth haemorrhage	9	
Oral blood blister	9	1
Oral purpura	1	0
Oral soft tissue infections		
Angular cheilitis	1	0
Oral soft tissue signs and symptoms		
Anaesthesia oral	1	0
Burning mouth syndrome	5	
Coating in mouth	1	0
Hypoaesthesia oral	350	
Lip discolouration	5	0
Lip erythema	2	
Lip exfoliation	5	
Lip pain	40	
Lip pruritus	10	
Lip scab	1	0
Oral discomfort	60	
Oral dysaesthesia	1	0
Oral mucosal blistering	12	
Oral mucosal discolouration	1	0
Oral mucosal eruption	11	0
Oral mucosal erythema	5	1
Oral mucosal exfoliation	7	0
Oral mucosal roughening	3	
Oral pain	123	
Oral pruritus	18	
Paraesthesia oral	714	0
Pigmentation lip	1	0
Oral soft tissue swelling and oedema		
Lip oedema	3	
Lip swelling	509	
Mouth swelling	64	0
Oedema mouth	4	0
Palatal oedema	2	0
Palatal swelling	1	0
Peptic ulcers and perforation		
Peptic ulcer	1	0
Peptic ulcer haemorrhage	9	0
Peritoneal and retroperitoneal disorders		
Ascites	1	0
Peritoneal and retroperitoneal fibrosis and adhesi	ons	
Abdominal adhesions	1	0
Peritoneal and retroperitoneal haemorrhages		

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

	A Version: MedDRA 24.0	
Reaction Name	<u>Total</u>	Fatal
Gastrointestinal disorders ointestinal disorders cont'd		
Haemoperitoneum	1	I 0
Retroperitoneal haemorrhage	1	1
Rectal inflammations NEC		
Proctitis	1	I 0
Proctitis ulcerative	1	
Salivary gland disorders NEC		-
Salivary gland disorder	1	I 0
Salivary gland pain	11	
Salivary gland enlargements		
Parotid gland enlargement	3	3 0
Salivary gland enlargement	3	
Submaxillary gland enlargement		
Salivary gland infections and inflammations		
Noninfective sialoadenitis		
Stomatitis and ulceration		0
Aphthous ulcer	32	
Lip ulceration	12	
Mouth ulceration	304	
Oral mucosa erosion		
Palatal ulcer	1	0
Stomatitis	45	5 0
Tongue disorders		
Glossitis	13	
Plicated tongue	2	2 0
Tongue disorder	29	
Tongue haemorrhage	2	2 0
Tongue ulceration	24	
Trichoglossia		1 0
Tongue signs and symptoms		
Glossodynia	152	
Scalloped tongue	Ę	5 0
Stiff tongue	3	3 0
Swollen tongue	364	4 O
Tongue blistering	15	5 0
Tongue coated	14	4 O
Tongue discolouration	24	4 O
Tongue discomfort	32	2 0
Tongue dry	12	2 0
Tongue eruption	3	
Tongue erythema	6	6 0
Tongue exfoliation		I O
Tongue movement disturbance	5	
Tongue oedema	19	
Tongue pruritus	1	i o
Tongue rough	2	
Tongue spasm	8	
	(1
<i>Tooth missing</i> Tooth loss		
Gastrointestinal disorders SOC TOTAL	24908	3 14

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968	MedDRA Version: MedDRA 24.0	.	
Reaction Name		<u>Fotal</u>	Fatal
General disorders			
Administration site reactions NEC		_	-
Administration site bruise		5	0
Administration site erythema		3	0
Administration site extravasation		2	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 impairm	ient	1	0
Administration site pain		12	0
Administration site rash		2	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
Adverse effect absent			
No adverse event		12	0
Application and instillation site reactions			
Application site acne		2	0
Application site bruise		5	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		11	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
Asthenic conditions			
Asthenia		1129	1
Chronic fatigue syndrome		55	0
Decreased activity		4	0
Fatigue		15062	0
Malaise		3356	0
Sluggishness		11	0
Body temperature altered			
Hyperthermia		5	0
Hypothermia		19	0
Temperature regulation disorder		7	0

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 24.0	-	
Reaction Name	<u> </u>	Fatal
General disorders General disorders cont'd		
Breast complications associated with device		
Capsular contracture associated with breast implant	1	0
Cardiac complications associated with device		
Prosthetic cardiac valve thrombosis	1	0
Complications associated with device NEC		
Capsular contracture associated with implant	1	0
Injury associated with device	2	
Medical device pain	1	0
Medical device site swelling	1	0
Phantom shocks	1	0
Death and sudden death		
Brain death	1	1
Clinical death	1	1
Death	128	128
Sudden death	25	
Febrile disorders	20	20
Hyperpyrexia	6	0
Pyrexia	9860	
Feelings and sensations NEC	0000	
	6441	0
Feeling abnormal	943	
Feeling cold	789	
Feeling drunk	57	
Feeling hot	760	
Feeling jittery	16	
Feeling of body temperature change	217	
Hangover	47	
Hunger	25	
Sensation of foreign body	36	
Temperature intolerance	23	
Thirst	230	
Fibrosis NEC	200	l u
Fibrosis	1	0
Gait disturbances		
Gait disturbance	112	0
Gait inability	46	
Loss of control of legs	10	
General signs and symptoms NEC	10	l u
Adhesion	1	0
Chronic disease	1	0
Condition aggravated	113	
Crepitations	1	0
Crying	87	
Deformity	2	
Discharge	5	0
Disease progression	2	
Disease recurrence	22	
Effusion	22	1
	13	
Energy increased Exercise tolerance decreased	13	-
	9	
Foaming at mouth	1	0
General physical health deterioration	13	
General symptom	2	0

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Reaction Name	MedDRA Version: MedDRA 24.0	Fatal
General disorders General disorders cont'd		
Glassy eyes High-pitched crying		3 0 2 0
Illness	114	-
Induration		
	1(
Influenza like illness	1579	
Irritability postvaccinal		2 0
Local reaction	6	
Moaning		2 0
Multiple organ dysfunction syndrome	4	4 2 1 0
Nonspecific reaction		
Organ failure		
Perforation		1 0
Peripheral swelling	2240	
Pre-existing condition improved	8	3 0
Prolapse		1 0
Screaming	14	
Secretion discharge	10	
Swelling	170	
Swelling face	562	
Symptom recurrence		1 0
Implant and catheter site reactions		
Implant site discolouration		2 0
Implant site pain		1 0
Implant site rash		1 0
Implant site swelling		1 0
Implant site urticaria		1 0
Implant site warmth		1 0
Inflammations		
Granuloma		1 0
Inflammation	244	4 0
Papillitis		1 0
Serositis		1 0
Systemic inflammatory response syndrome	e	1 0
Infusion site reactions		
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
Injection site reactions		
Injected limb mobility decreased	22	
Injection site bruising	49	9 0
Injection site coldness		1 0
Injection site cyst		2 0
Injection site discolouration		5 0
Injection site discomfort	9	9 0
Injection site erythema	26	1 0
Injection site haemorrhage	(6 0
Injection site hypersensitivity		1 0
Injection site hypoaesthesia	8	3 0
Injection site indentation		5 0

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968 Reaction Name	MedDRA Version: MedDRA 24.0 Total	Fatal
General disorders General disorders cont'd	Total	<u> </u>
Injection site induration		3 0
,		
Injection site inflammation	20	6 0 1 0
Injection site joint discomfort		
Injection site joint movement impairment	11	1 0
Injection site joint pain		
Injection site lymphadenopathy		1 0
Injection site macule	201	1 0
Injection site mass	33	
Injection site movement impairment		1 0
Injection site necrosis		3 0
Injection site oedema	1	
Injection site pain	213	
Injection site paraesthesia	1	
Injection site pruritus	128	
Injection site rash	103	
Injection site reaction	2	
Injection site scab		2 0
Injection site scar		4 0
Injection site swelling	220	
Injection site urticaria	18	
Injection site vesicles		7 0
Injection site warmth	12	7 0
Interactions		
Alcohol interaction		2 0
Drug interaction	10	
Inhibitory drug interaction		3 0
Mass conditions NEC		
Cyst	23	
Mass	40	
Nodule	20	6 0
Mucosal findings abnormal		
Mucosa vesicle		1 0
Mucosal dryness		1 0
Mucosal haemorrhage	5	8 0
Mucosal inflammation		2 0
Oedema mucosal		1 0
Polyp		2 0
Necrosis NEC		
Fat necrosis		2 0
Necrosis		3 0
Oedema NEC		_
Face oedema	2	
Generalised oedema		1 0
Localised oedema	11	
Oedema	42	
Oedema peripheral	59	9 0
Pain and discomfort NEC		
Axillary pain	1612	
Chest discomfort	968	
Chest pain	2019	9 1
Discomfort	239	e o
Facial discomfort	14	4 O
Facial pain	142	

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968 Reaction Name	MedDRA Version: MedDRA 24.0	Total	Fatal
General disorders General disorders cont'd			i atai
Inflammatory pain		5	0
Non-cardiac chest pain		19	0
Pain		5305	0
Suprapubic pain		1	0
Tenderness		448	0
Visceral pain		1	0
Therapeutic and nontherapeutic responses			0
Adverse drug reaction		22	0
Adverse event		3	0
Adverse food reaction		1	0
Adverse reaction		1	0
Drug ineffective		167	1
Drug intolerance		2	0
Immediate post-injection reaction		2	0
Inadequate analgesia		2	0
No reaction on previous exposure to drug		37	0
Product intolerance		1	0
Therapeutic product effect delayed		2	0
Therapeutic product effect increased		2	0
Therapeutic product ineffective		2	0
Therapeutic product menective Therapeutic response decreased		2	0
Therapeutic response unexpected		49	0
Treatment failure			
Vaccination failure		6 8	0
		0	U
Trophic disorders		1	0
Atrophy Calcinosis		1	0
		- 1	0
Ulcers NEC		45	0
Ulcer		15	0
Ulcer haemorrhage		1	0
Vaccination site reactions			0
Extensive swelling of vaccinated limb		9	0
Shoulder injury related to vaccine administ	ration	16	0
Vaccination site bruising		80	0
Vaccination site coldness		1	0
Vaccination site cyst		4	0
Vaccination site dermatitis		1	0
Vaccination site discolouration		10	0
Vaccination site discomfort		35	0
Vaccination site dryness		1	0
Vaccination site eczema		1	0
Vaccination site erythema		436	0
Vaccination site granuloma		1	0
Vaccination site haematoma		1	0
Vaccination site haemorrhage		13	0
Vaccination site hypersensitivity		2	0
Vaccination site hypoaesthesia		11	0
Vaccination site induration		63	C
Vaccination site inflammation		46	0
Vaccination site irritation		10	0
Vaccination site joint discomfort		2	C
Vaccination site joint erythema		7	0
Vaccination site joint inflammation		1	C

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 24.0		
Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site joint movement impairment	15	0
Vaccination site joint pain	25	0
Vaccination site joint swelling	2	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	3	0
Vaccination site macule	1	0
Vaccination site mass	176	0
Vaccination site movement impairment	58	0
Vaccination site nerve damage	1	0
Vaccination site nodule	2	0
Vaccination site oedema	3	0
Vaccination site pain	1559	0
Vaccination site paraesthesia	4	0
Vaccination site pruritus	112	0
Vaccination site rash	91	0
Vaccination site reaction	27	0
Vaccination site scab	1	0
Vaccination site scar	1	0
Vaccination site swelling	419	0
Vaccination site ulcer	1	0
Vaccination site urticaria	8	0
Vaccination site vesicles	3	0
Vaccination site warmth	209	0
Vascular complications associated with device		
Vascular stent thrombosis	1	0
Withdrawal and rebound effects		
Drug withdrawal syndrome	4	0
Withdrawal syndrome	22	0
General disorders SOC TOTAL	65879	162

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

	MedDRA Version: MedDRA 24.0	
Reaction Name	Total	Fatal
Hepatic disorders		
Bile duct infections and inflammations		
Biliary colic	Ę	5 0
Cholangitis	1	I 0
Cholecystitis and cholelithiasis		
Cholecystitis acute	1	I 0
Cholelithiasis	6	6 0
Cholestasis and jaundice		
Cholestasis	2	2 0
Jaundice	14	4 O
Jaundice cholestatic	Ę	
Gallbladder disorders NEC		
Gallbladder disorder		I 0
Hepatic and hepatobiliary disorders NEC		
Liver disorder	3	3 0
Hepatic enzymes and function abnormalities		
Hepatic function abnormal		
Hepatic failure and associated disorders		
Acute hepatic failure		I 0
Hepatic failure		2 1
Hepatic fibrosis and cirrhosis		
Hepatic cirrhosis		I 0
Hepatic vascular disorders		
Congestive hepatopathy		ı o
Hepatic artery embolism		I 0
Hepatic haemorrhage		2 0
Hepatic vein thrombosis	4	
Portal vein thrombosis	3	
Hepatobiliary signs and symptoms		
Hepatic pain	18	3 0
Hepatomegaly		
Liver tenderness	3	
Hepatocellular damage and hepatitis NEC		
Autoimmune hepatitis	2	4 O
Drug-induced liver injury		
Hepatitis	ç	
Immune-mediated hepatic disorder		
Liver injury	8	
Hepatic disorders SOC TOTAL	105	

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968	MedDRA Version: MedDRA 24.0	E ctal
Reaction Name	Total	Fatal
Immune system disorders		
Acute and chronic sarcoidosis		
Sarcoidosis	10	0 0
Allergic conditions NEC		
Allergic oedema	1'	
Allergy to animal		0
Allergy to arthropod bite	2	2 0
Allergy to arthropod sting		0
Allergy to metals		0
Allergy to sting		0
Hypersensitivity	649	
Mite allergy		0
Multiple allergies		6 0
Serum sickness		2 0
Serum sickness-like reaction		3 0
Type I hypersensitivity		0
Type III immune complex mediated reactio		0
Type IV hypersensitivity reaction	(6 0
Allergies to foods, food additives, drugs and		
Allergic reaction to excipient	4	
Allergy to chemicals		
Allergy to vaccine	27	
Contrast media reaction		
Drug hypersensitivity	18	
Food allergy	15	
Oral allergy syndrome		
Reaction to colouring		I 0
Reaction to excipient		
Reaction to preservatives	4	1 O
Rubber sensitivity		0 0
Anaphylactic and anaphylactoid responses		
Anaphylactic reaction	376	
Anaphylactic shock	34	
Anaphylactoid reaction	19	
Anaphylactoid shock		4 O
Atopic disorders		
Atopy		
Seasonal allergy	63	3 0
Autoimmune disorders NEC		
Autoimmune disorder	20	6 0
Immune and associated conditions NEC		
Bacille Calmette-Guerin scar reactivation	29	
Graft versus host disease		0
Immune system disorder	16	
Immune-mediated adverse reaction		5 0
Immunisation reaction		1 C
Sensitisation		3 C
Systemic immune activation		2 C
Immunodeficiency disorders NEC		
Hypogammaglobulinaemia	· · · · · · · · · · · · · · · · · · ·	
Immunodeficiency		I 0
Immunosuppression		
Transplant rejections		
Corneal graft rejection		5 C

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

Report Run Date: 15-Jul-2021	Data Lock Date: 14-Jul-2021 18:30	:32	
Earliest Reaction Date: 13-Apr-1968	MedDRA Version: MedDRA 24.0		
Reaction Name		Total	Fatal
Immune system disordersne system disorder	rs cont'd		
Kidney transplant rejection		1	0
Solid organ transplant rejection		1	0

Immune system disorders SOC TOTAL

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0 0

2

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Reaction Name	MedDRA Version: MedDRA 24.0	otal	Fatal
Infections			i atai
Abdominal and gastrointestinal infections			
Abdominal abscess		1	0
Abdominal infection		1	0
Anal abscess		3	0
Appendicitis		22	0
Appendicitis perforated		22	0
Diverticulitis		2 5	0
Dysentery		1	0
Gastric infection		2	
Gastroenteritis		21	0
		21	-
Mesenteric abscess		1	0
Peritonitis		1	1
Rectal abscess		1	0
Adenoviral infections		4	0
Adenoviral conjunctivitis		1	0
Aspergillus infections		4	0
Bronchopulmonary aspergillosis		1	0
Bacterial infections NEC			0
Abscess bacterial		1	0
Arthritis bacterial		3	0
Bacterial colitis		1	0
Bacterial diarrhoea		1	0
Bacterial infection		407	0
Cellulitis		127	0
Conjunctivitis bacterial		1	0
Ear infection bacterial		1	0
Folliculitis		10	0
Gangrene		1	0
Injection site cellulitis		2	0
Meningitis bacterial		3	0
Paronychia Perichondritis		2	0
Periorbital cellulitis		1	0
Sinusitis bacterial		1	0
		4	0
Skin bacterial infection Tonsillitis bacterial		1	0
		3	0
Urinary tract infection bacterial Vaccination site cellulitis		15	0
Zoonotic bacterial infection		10	1
Bartonella infections		1	I
Cat scratch disease		1	0
Bone and joint infections		1	0
Abscess jaw		1	0
Osteomyelitis		1	0
Borrelial infections			0
Lyme disease		1	0
Relapsing fever		1	0
Breast infections		1	0
Breast abscess		2	0
Mastitis		2 42	0
Caliciviral infections		42	U
Gastroenteritis norovirus		4	0
		1	0
Campylobacter infections			

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Reaction Name	Total	Fatal
Infections Infections cont'd		
Campylobacter gastroenteritis	1	0
Candida infections		
Anal candidiasis	2	0
Candida infection	37	
Oral candidiasis	32	
Systemic candida	1	0
Vulvovaginal candidiasis	32	. 0
Cardiac infections		
Pericarditis infective	1	0
Central nervous system and spinal infections		
CNS ventriculitis	1	0
Cavernous sinus thrombosis	1	0
Encephalitis	14	0
Meningitis	4	. 0
Meningitis aseptic	1	0
Myelitis	4	
Clostridia infections		
Clostridium difficile infection	2	. 0
Coronavirus infections		
Asymptomatic COVID-19	11	0
COVID-19	781	
COVID-19 pneumonia	34	1
Coronavirus infection	6	
Post-acute COVID-19 syndrome	1	0
Severe acute respiratory syndrome	1	0
Suspected COVID-19	44	
Coxiella infections		
Q fever	g	0
Cytomegaloviral infections		
Cytomegalovirus infection	2	. 0
Cytomegalovirus syndrome	1	
Dental and oral soft tissue infections		
Abscess oral	4	. 0
Gingivitis	7	0
Parotitis	8	
Pulpitis dental	1	0
Sialoadenitis	3	
Tooth abscess	8	
Tooth infection	7	
Ear infections		
Ear infection	54	. 0
Labyrinthitis	68	
Mastoiditis	1	0
Otitis media	3	0
Otitis media acute	1	0
Ectoparasitic infestations		
Acarodermatitis	4	. 0
Bed bug infestation	1	
Epstein-Barr viral infections		
Epstein-Barr virus infection		c c
Infectious mononucleosis	21	
Eye and eyelid infections		
Conjunctivitis	50) C

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

	IDRA Version: MedDRA 24.0	Catal
Reaction Name	Total	Fatal
Eye abscess	1	
Eye infection	15	
Eyelid infection	2	-
Hordeolum	17	1
Periorbital infection	2	0
Female reproductive tract infections		
Bartholinitis	1	0
Endometritis	2	
Funisitis	1	0
Pelvic inflammatory disease	1	0
Vaginal infection	1	0
Vulval abscess	1	0
Fungal infections NEC		
Fungal infection	8	1
Fungal skin infection	2	
Onychomycosis	1	0
Oral fungal infection	1	0
Pneumonia fungal	2	
Vulvovaginal mycotic infection	5	0
Hepatitis virus infections		
Hepatitis A	1	0
Hepatitis E	1	0
Hepatobiliary and spleen infections		
Biliary sepsis	1	0
Cholecystitis infective	1	0
Herpes viral infections		
Disseminated varicella zoster virus infection	1	0
Eczema herpeticum	2	-
Genital herpes	64	
Genital herpes simplex	5	1
Herpes ophthalmic	3	0
Herpes simplex	22	0
Herpes simplex encephalitis	1	1
Herpes simplex reactivation	2	
Herpes virus infection	9	U 0
Herpes zoster	1083	-
Herpes zoster meningoencephalitis	1	0
Herpes zoster oticus	9	-
Herpes zoster reactivation	1	0
Nasal herpes	3	0
Ophthalmic herpes zoster	3	0
Oral herpes	229	
Varicella	19	
Varicella zoster virus infection	1	0
Infections NEC		
Abscess	27	0
Abscess limb	4	0
Abscess soft tissue	1	0
Genital abscess	1	0
Infected bite	1	0
Infected cyst	2	0
Infection	159	0
Injection site abscess	1	0

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968	MedDRA Version: MedDRA 24.0	
Reaction Name	Total	Fatal
Infections Infections cont'd		
Injection site infection		5 0
Localised infection	1,	8 0
Lymph gland infection		6 0
Lymph node abscess		4 0
Opportunistic infection		1 0
Respiratory tract infection		6 0
Vaccination site abscess		5 0
Vaccination site infection	1:	2 0
Vaccine breakthrough infection	2	
Vestibulitis		2 0
Wound infection		1 0
Infectious transmissions		
Secondary transmission		8 0
Influenza viral infections		
Influenza	103	4 0
Klebsiella infections	100	Ĭ
Klebsiella infection		1 0
Lower respiratory tract and lung infections		
Bronchitis	1	6 0
Infectious pleural effusion		1 0
Lower respiratory tract infection	13	
Pneumonia	8	
Sputum purulent	0	1 0
Male reproductive tract infections		3 0
Epididymitis Orchitis		
Prostate infection		3 0 1 0
Mumps viral infections		
Mumps		6 0
Muscle and soft tissue infections		
Abscess neck		1 0
Infective tenosynovitis		1 0
Necrotising fasciitis		2 0
Soft tissue infection		1 0
Neisseria infections		
Gonorrhoea		1 0
Pneumocystis infections		
Pneumocystis jirovecii pneumonia		1 0
Retroviral infections		
HIV infection		1 0
Rotaviral infections		
Gastroenteritis rotavirus		1 0
Rubeola viral infections		
Measles		3 0
Sepsis, bacteraemia, viraemia and fungaem	ia NEC	
Bacteraemia		1 0
Neutropenic sepsis		3 1
Sepsis	3	
Sepsis syndrome		1 0
Septic rash		1 0
Septic shock		4 1
Urosepsis		5 0
Skin structures and soft tissue infections		

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0	
Total	Fatal
1	0
1	0
1	0
2	0
5	0
1	0
1	0
1	0
g	0
9	0
26	0
6	0
4	0
29	0
1	0
1	0
2	
1	0
1	0
5	
1	0
1	0
1	0
1	0
1	0
1	0
1	0
1	0
1	0
1	0
1	0
1	0
1	0
3	0
1	0
1	0
17	0
606	0
2	0
21	0
	0
1	
	Total Total Total

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Reaction Name	Tota	I .	Fatal
Infections Infections cont'd		\square	
Urinary tract infections			
Cystitis		55	0
Kidney infection		26	0
Pyelonephritis		1	0
Urinary tract infection	1 ⁻	18	0
Vascular infections		_	
Haematoma infection		1	0
Infected lymphocele		1	0
Infusion site infection		1	0
Lymphangitis		7	0
Viral infections NEC			-
Arthritis viral		1	0
Conjunctivitis viral		2	0
Encephalitis viral		3	0
Eye infection viral		2	0
Gastroenteritis viral		17	0
Hepatitis viral		2	0
Meningitis viral Oral viral infection		4	0
Pleurisy viral			
Pneumonia viral		2	0
Post viral fatigue syndrome		30	0
Sweating fever		50 67	0
Vestibular neuronitis		19	0
Viral diarrhoea		2	0
Viral infection		35	0
Viral labyrinthitis		3	0
Viral pericarditis		1	0
Viral pharyngitis		13	0
Viral rash		36	0
Viral sinusitis		1	0
Viral tonsillitis		1	0
Infections SOC TOTAL	610	66	75

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Reaction Name	Total	Fatal
Injuries		I atai
Abdominal and gastrointestinal injuries NEC		
Mouth injury	3	0
Oral contusion	2	0
Palate injury	1	0
Rectal injury	1	0
Splenic rupture	5	0
Tongue injury	1	0
Tooth fracture	1	0
Tooth injury	1	0
Accidental exposures to product		Ŭ
Accidental exposure to product	15	0
Anaesthetic and allied procedural complications	10	Ū
Airway complication of anaesthesia	1	0
Delayed recovery from anaesthesia	2	0
Sedation complication	1	0
Atmospheric pressure injuries		Ū
Barotitis media	1	0
Hypobarism	1	0
Bone and joint injuries NEC		Ŭ
Joint injury	4	0
Cardiovascular injuries		Ŭ
Heart injury	4	0
Vascular injury	4	0
Cerebral injuries NEC		Ŭ
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
Chemical injuries		
Chemical cystitis	1	0
Chest and respiratory tract injuries NEC		
Chest crushing	8	0
Foreign body in throat	1	0
Conditions caused by cold		
Chillblains	48	0
Cranial nerve injuries		
Vth nerve injury	1	0
Ear injuries NEC		
Ear injury	1	0
Exposures associated with pregnancy, delivery and lactation		
Exposure during pregnancy	7	0
Exposure via breast milk	30	0
Foetal exposure during pregnancy	14	0
Maternal exposure before pregnancy	2	0
Maternal exposure during breast feeding		0
Maternal exposure during pregnancy	406	0
Maternal exposure timing unspecified	1	0
Paternal exposure before pregnancy	2	0
Exposures to agents or circumstances NEC	2	0

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 24.		
Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Exposure to SARS-CoV-2	1	0
Exposure to vaccinated person	3	0
Eye and ear procedural complications		
Toxic anterior segment syndrome	1	0
Eye injuries NEC		
Eye contusion	13	0
Eye injury	11	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
Foetal and neonatal conditions associated with product exposure		Ŭ
Intoxication by breast feeding	1	0
Fractures and dislocations NEC		0
Bone fragmentation	1	0
Fracture	1	0
Joint dislocation	2	0
Multiple fractures	2	0
		0
Gastrointestinal and hepatobiliary procedural complications	1	0
Post procedural constipation	1	0
Postoperative ileus		0
Procedural nausea	6	0
Procedural vomiting	1	0
Heat injuries (excl thermal burns)		
Heat cramps	1	0
Heat exhaustion	2	0
Heat illness	1	0
Heat oedema	7	0
Heat stroke	3	0
Intentional product use issues		-
Intentional product use issue	1	0
Limb fractures and dislocations		
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
Medication errors, product use errors and issues NEC		
Circumstance or information capable of leading to medication error	1	0
Dose calculation error	1	0
Inadequate aseptic technique in use of product	1	0
Medication error	17	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
Muscle, tendon and ligament injuries	- U	
Epicondylitis	12	C

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 24.0 Reaction Name MedDRA Version: MedDRA 24.0	Total	Fatal
Injuries Injuries cont'd	Total	Γαιαι
Ligament sprain	6	0
Mallet finger	1	0
Manet iniger Muscle injury	12	0
Muscle rupture	2	0
Muscle strain	21	0
Post-traumatic neck syndrome	1	0
Tendon injury	5	0
Tendon rupture	4	0
Musculoskeletal procedural complications		-
Periprosthetic osteolysis	1	0
Post laminectomy syndrome	1	0
Nerve injuries NEC		
Nerve injury	40	0
Neurological and psychiatric procedural complications		
Post procedural stroke	1	0
Procedural dizziness	11	0
Non-occupational environmental exposures		
Exposure to extreme temperature	1	0
Non-site specific injuries NEC		
Arthropod bite	2	0
Arthropod sting	3	0
Bite	1	0
Electric shock	9	0
Fall	102	1
Foreign body	2	0
Injury	5	0
Nervous system injury	1	0
Post concussion syndrome	1	0
Traumatic haematoma	1	
Wound	5	0
	5	
Wound complication	8	0
Wound haematoma	1	0
Wound haemorrhage	2	0
Wound secretion	3	0
Non-site specific procedural complications		
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
Occupational exposures		
Occupational exposure to SARS-CoV-2	1	0
Occupational exposure to product	1	0
Off label uses		
Off label use	44	0
Overdoses NEC		
Overdose	25	0
Pathways and sources of exposure		
Exposure via unknown route	1	0
Pelvic fractures and dislocations		Ū
Pelvic fracture	1	0
Peripheral nerve injuries		0

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 24.0		
Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Brachial plexus injury	1	0
Ulnar nerve injury	4	0
Poisoning and toxicity		
Alcohol poisoning	1	0
Poisoning	9	0
Toxicity to various agents	2	0
Product administration errors and issues		
Accidental overdose	3	0
Contraindicated product administered	1	0
Expired product administered	10	0
Inappropriate schedule of product administration	148	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	3	0
Poor quality product administered	2	0
Product administered at inappropriate site	10	0
Product administered to patient of inappropriate age	1	0
Product administration error	5	0
Product dose omission issue	3	0
Wrong product administered	16	0
Product confusion errors and issues		
Product label confusion	1	0
Product dispensing errors and issues		
Product dispensing error	3	0
Product monitoring errors and issues		
Drug monitoring procedure incorrectly performed	1	0
Product preparation errors and issues		
Product preparation error	1	0
Product preparation issue	5	0
Product prescribing errors and issues		
Contraindicated product prescribed	2	0
Product selection errors and issues		
Product selection error	2	0
Radiation injuries		
Sunburn	16	0
Renal and urinary tract injuries NEC		
Foreign body in urogenital tract	1	0
Site specific injuries NEC		
Face crushing	1	0
Head injury	29	0
Limb crushing injury	2	0
Limb injury	58	0
Nasal injury	1	0
Neck crushing	1	0
Neck injury	1	C
Skin injuries NEC		
Contusion	736	C
Nail avulsion	1	C
Scar	7	C
Scratch	7	C
Skin abrasion	5	C

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Skin injury	1	0
Skin wound	2	0
Subcutaneous haematoma	1	0
Skull fractures, facial bone fractures and dislocations		
Fractured skull depressed	1	0
Spinal fractures and dislocations		
Spinal fracture	3	0
Stoma complications		
Gastrointestinal stoma complication	1	0
Stoma site discharge	1	0
Stoma site extravasation	1	0
Stoma site haemorrhage	1	0
Thermal burns		
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	13	0
Thermal burns of eye	9	0
Underdoses NEC		
Underdose	6	0
Vaccination related complications		
Adverse event following immunisation	1	0
Vaccination complication	41	0
Injuries SOC TOTAL	3248	2

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 24.		
Reaction Name	Total	Fatal
Investigations		
Adrenal cortex tests		
Cortisol decreased	3	0
Adrenal medulla tests		
Epinephrine increased	1	0
Auditory and vestibular diagnostic procedures	-	
Acoustic stimulation tests	5	0
Audiogram abnormal	1	0
Autoimmunity analyses		
Antinuclear antibody	1	0
Antinuclear antibody increased	1	0
Rheumatoid factor	3	0
Blood counts NEC		
Blood count	4	0
Blood count abnormal	2	0
Blood gas and acid base analyses	_	-
Acid base balance abnormal	1	0
Blood lactic acid	2	0
Blood lactic acid decreased	1	0
Blood lactic acid increased	2	0
Blood pH	6	0
Blood pH increased	6	0
Oxygen consumption decreased	1	0
Oxygen saturation	6	0
Oxygen saturation decreased	48	0
Bone marrow and immune tissue histopathology procedures	_	
Aspiration bone marrow	1	0
Biopsy lymph gland	1	0
Bone marrow and immune tissue imaging procedures		
Lymph nodes scan abnormal	1	0
Scan lymph nodes	4	0
Carbohydrate tolerance analyses (incl diabetes)	_	
Blood glucose	6	0
Blood glucose abnormal	9	0
Blood glucose decreased	25	0
Blood glucose fluctuation	14	0
Blood glucose increased	82	0
Glycosylated haemoglobin increased	1	0
Cardiac auscultatory investigations		
Cardiac murmur	13	
Heart sounds	2	0
Heart sounds abnormal	3	0
Cardiac function diagnostic procedures		
Cardiac monitoring	1	0
Cardiac output	1	0
Central venous pressure	1	0
Echocardiogram	1	0
Stroke volume decreased	1	0
Cardiac imaging procedures		
Magnetic resonance imaging heart	1	0
Scan myocardial perfusion abnormal	1	0
Cell marker analyses		
Prostatic specific antigen increased	2	0
Central nervous system imaging procedures		

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968	MedDRA Version: MedDRA 24.0		
Reaction Name		<u>Total</u>	Fatal
Investigations Investigations cont'd			
Computerised tomogram head		4	0
Magnetic resonance imaging head		11	0
Magnetic resonance imaging head abnor	mal	1	0
Cerebrospinal fluid tests (excl microbiology			
CSF pressure		1	0
Chemistry analyses NEC			·
Inflammatory marker increased		3	0
Renin		1	0
Cholesterol analyses			Ŭ
Blood cholesterol increased		4	0
Remnant-like lipoprotein particles		3	0
Coagulation and bleeding analyses		5	0
Activated partial thromboplastin time pro-	angod	15	0
		10	-
Activated partial thromboplastin time sho Bleeding time	lened	1	0
		1	-
Bleeding time abnormal		1	0
Bleeding time prolonged		3	0
Blood thromboplastin		1	0
Clot retraction		1	1
Coagulation factor VIII level decreased		1	0
Coagulation time prolonged		8	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
ECG investigations		-	-
Electrocardiogram	-	2	0
Electrocardiogram QRS complex prolong	ed	1	0
Electrocardiogram QT prolonged		2	0
Electrocardiogram ST segment elevation		3	0
Electrocardiogram ST-T segment abnorm	al	1	0
Electrocardiogram T wave inversion		3	0
Electrocardiogram abnormal		11	0
Electrocardiogram normal		2	0
QRS axis abnormal		1	0
Endocrine analyses and imaging NEC			
Hormone level abnormal		25	0
Faecal analyses NEC			
Faecal calprotectin		2	0
Faecal calprotectin increased		4	0
Fertility analyses			
Infertility tests		1	0
Semen analysis abnormal		1	0
Foetal and neonatal diagnostic procedures			
Foetal heart rate abnormal		2	2
Foetal heart rate increased		1	0
Foetal non-stress test		1	0
Gastrointestinal and abdominal imaging pro	ocedures		
Computerised tomogram abdomen		1	0
Sigmoidoscopy abnormal		1	0
Gastrointestinal function diagnostic proced	ires		Ŭ

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968	MedDRA Version: MedDRA 24.0	
Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Gastric pH decreased	· · · · · · · · · · · · · · · · · · ·	1 0
Gastrointestinal, pancreatic and APUD horn	none analyses	
Blood insulin	· · · · · · · · · · · · · · · · · · ·	1 0
Blood insulin decreased		1 0
Haematological analyses NEC		
Plasma viscosity		1 0
Red blood cell sedimentation rate increase	ed	5 0
Heart rate and pulse investigations		
Carotid pulse		1 0
Heart rate	25	
Heart rate abnormal	30	
Heart rate decreased	40	
Heart rate increased	510	
Heart rate irregular	99	
Maximum heart rate	9	1 0
Pulse abnormal	1:	
Pulse pressure increased		1 0
Radial pulse abnormal		1 0
Sinus rhythm	· · · · · · · · · · · · · · · · · · ·	4 0
Imaging procedures NEC		
Computerised tomogram		2 0
Magnetic resonance imaging		1 0
Magnetic resonance imaging abnormal		1 0
Immunoglobulin analyses		
Blood immunoglobulin G increased		1 0
Blood immunoglobulin M		1 0
Blood immunoglobulin M increased		1 0
Immunology analyses NEC		
Antibody test		4 0
Immunology test		7 0
Immunology skin tests NEC		
Skin test positive		1 0
Investigations NEC		
Blood test		9 0
Blood test abnormal	2	
False positive investigation result	· · · · · · · · · · · · · · · · · · ·	1 0
Laboratory test	· · · · · · · · · · · · · · · · · · ·	1 0
Polymerase chain reaction positive	33	3 0
Systemic lupus erythematosus disease ac	tivity index increased	1 0
Liver function analyses		
Alanine aminotransferase increased	18	3 0
Aspartate aminotransferase	· · · · · · · · · · · · · · · · · · ·	1 0
Aspartate aminotransferase increased		2 0
Blood bilirubin increased		2 0
Gamma-glutamyltransferase increased		4 0
Hepatic enzyme increased		4 0
Liver function test	· · · · · · · · · · · · · · · · · · ·	1 0
Liver function test abnormal	19	
Liver function test increased	1:	
Transaminases increased		2 0
Metabolism tests NEC		Ī
Blood ketone body		3 0
Blood ketone body increased		1 0

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

	MedDRA Version: MedDRA 24.0	
Reaction Name	Total	<u>Fatal</u>
Investigations Investigations cont'd		
Blood uric acid increased	2	2 0
Brain natriuretic peptide increased	1	0
Ubiquinone	1	0
Microbiology and serology tests NEC		
Culture negative	1	0
Mineral and electrolyte analyses		
Blood copper increased	1	0
Blood iron	1	0
Blood iron decreased		8 0
Blood magnesium decreased	1	0
Blood phosphorus decreased	1	0
Blood phosphorus increased	1	0
Blood potassium abnormal	1	0
Blood potassium decreased	4	0
Blood potassium increased	2	2 0
Blood sodium decreased	8	
Serum ferritin	1	0
Serum ferritin decreased		8 0
Serum ferritin increased	1	0
Musculoskeletal and soft tissue imaging proce	dures	
Skull X-ray	6	6 0
Musculoskeletal and soft tissue tests NEC		
Swollen joint count increased	1	0
Mycobacteria identification and serology		
Tuberculin test positive	1	0
Neurologic diagnostic procedures		
Coma scale abnormal	3	8 0
Hoover's sign of leg paresis	1	0
Lumbar puncture	3	8 0
Temperature perception test increased	1	0
Ophthalmic function diagnostic procedures		
Corneal reflex decreased	1	0
Intraocular pressure increased	7	/ 0
Physical examination procedures and organ s	ystem status	
Body temperature	185	5 0
Body temperature abnormal	30	0 0
Body temperature decreased	30	0 0
Body temperature fluctuation	23	8 0
Body temperature increased	294	l 0
Body temperature normal	1	0
Breath sounds abnormal	1	0
General physical condition abnormal	1	0
Grip strength	2	2 0
Grip strength decreased	13	8 0
Head lag	3	8 0
Lymph node palpable	30	0 0
Menstruation normal	2	2 0
Muscle strength abnormal	1	0
Ophthalmological examination	2	
Palpatory finding abnormal		0
Product residue present	2	
Psoriasis area severity index decreased		0
Respiratory rate	7	

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 24.0		
Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Respiratory rate decreased	9	0
Respiratory rate increased	26	0
Skin temperature	26	0
Temperature difference of extremities	7	0
Weight	1	0
Weight decreased	57	0
Weight increased	14	0
Pituitary analyses anterior		
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
Platelet analyses		
Mean platelet volume decreased	1	0
Platelet count	1	0
Platelet count decreased	52	0
Platelet count increased	1	0
Protein analyses NEC		
Alpha 1 globulin decreased	1	0
Alpha 2 globulin decreased	1	0
C-reactive protein increased	15	0
Red blood cell analyses		
Haematocrit	1	0
Haemoglobin decreased	10	0
Renal function analyses		
Blood creatinine increased	1	0
Glomerular filtration rate decreased	2	0
Reproductive hormone analyses		
Anti-Muellerian hormone level decreased	1	0
False negative pregnancy test	6	0
Female sex hormone level	1	0
Pregnancy test	15	0
Pregnancy test positive	1	0
Reproductive organ and breast histopathology procedures		
Smear cervix	1	0
Reproductive organ and breast imaging procedures		
Hysteroscopy	2	0
Respiratory and pulmonary function diagnostic procedures		
Forced expiratory volume increased	2	0
Maximal voluntary ventilation	1	0
Peak expiratory flow rate	1	0
Peak expiratory flow rate decreased	4	0
Pulmonary function test	2	0
Total lung capacity decreased	1	0
Vital capacity	1	0
Respiratory tract and thoracic histopathology procedures		
Sputum abnormal	3	0
Respiratory tract and thoracic imaging procedures		
Chest X-ray	18	0
Chest X-ray normal	1	0

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968	MedDRA Version: MedDRA 24.0		
Reaction Name	Tota	al ,	Fatal
Investigations Investigations cont'd			
Chest scan		1	0
Computerised tomogram thorax		1	0
Skeletal and cardiac muscle analyses			
Blood creatine phosphokinase increased		4	0
Myocardial necrosis marker		1	0
Troponin		1	0
Troponin increased		6	0
Therapeutic drug monitoring analyses		Ŭ	Ū
Analgesic drug level		4	0
Anticoagulation drug level above therapeut	ic	1	0
Anticoagulation drug level below therapeut		5	0
Anticoagulation drug level increased	5 	1	0
Drug level decreased		1	0
Thyroid analyses			0
Anti-thyroid antibody		1	0
Thyroid function test abnormal		3	0
Thyroxine free increased		2	0
Tri-iodothyronine		2	0
		3	0
Tri-iodothyronine decreased		ు	0
Tissue enzyme analyses NEC		2	0
Blood alkaline phosphatase increased		2	0
Toxicology laboratory analyses		4	0
Blood caffeine decreased		1	0
Drug screen positive		2	0
Opiates		1	0
Urinalysis NEC		10	0
Blood urine		10	0
Blood urine present		31	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
Urinary tract function analyses NEC			
Urine output		10	0
Urine output decreased		7	0
Urine output increased		4	0
Urinary tract imaging procedures		-	-
Cystoscopy		2	0
Vascular imaging procedures NEC			
Venogram		1	0
Vascular tests NEC (incl blood pressure)		_	
Blood pressure abnormal		5	0
Blood pressure decreased		46	0
Blood pressure diastolic		1	0
Blood pressure diastolic decreased		1	0
Blood pressure diastolic increased		2	0
Blood pressure increased	· · · · · · · · · · · · · · · · · · ·	162	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

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Virus identification and serology		
Coronavirus test	11	1 0
Coronavirus test positive		3 0
HIV test		1 0
SARS-CoV-1 test positive	· · · · · · · · · · · · · · · · · · ·	1 0
SARS-CoV-2 antibody test	(
SARS-CoV-2 antibody test negative	12	2 0
SARS-CoV-2 antibody test positive		
SARS-CoV-2 test	22	2 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	86	6 0
Viral test	4	4 0
Vitamin analyses		
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		2 0
Water and electrolyte analyses NEC		
Volume blood	· · · · · · · · · · · · · · · · · · ·	1 0
White blood cell analyses		
Lymphocyte count		1 0
Lymphocyte count decreased		1 0
Neutrophil count	· · · · · · · · · · · · · · · · · · ·	1 0
Neutrophil count decreased	4	4 0
White blood cell count		3 0
White blood cell count decreased	8	3 0
White blood cell count increased	6	5 O
Investigations SOC TOTAL	3155	5 3

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Reaction Name	1	<u>otal</u>	Fatal
Metabolic disorders			
Appetite disorders			-
Appetite disorder		11	0
Decreased appetite		818	0
Diet refusal		1	C
Eating disorder symptom		2	C
Food craving		8	C
Food refusal		6	C
Hyperphagia		6	C
Hypophagia		11	C
Increased appetite		19	C
Salt craving		2	C
Calcium metabolism disorders			
Hypocalcaemia		3	C
Tetany		2	0
Diabetes mellitus (incl subtypes)			
Diabetes mellitus		33	0
Diabetes mellitus inadequate control		9	1
Increased insulin requirement		1	0
Insulin resistant diabetes		1	0
Latent autoimmune diabetes in adults		2	C
Type 1 diabetes mellitus		13	0
Type 2 diabetes mellitus		2	0
Diabetic complications NEC			
Diabetic complication		2	0
Diabetic ketoacidosis		11	0
Diabetic ketosis		1	0
Disorders of purine metabolism			
Gout		67	0
Electrolyte imbalance NEC			
Fluid imbalance		1	0
Fat soluble vitamin deficiencies and disorders			
Vitamin D deficiency		1	0
Fluid intake increased			
Polydipsia		5	0
Food malabsorption and intolerance syndromes	s (excl sugar intolerance)		
Alcohol intolerance		2	C
Dairy intolerance		1	0
Food intolerance		7	C
Gluten sensitivity		4	C
Histamine intolerance		3	C
General nutritional disorders NEC			
Abnormal loss of weight		9	C
Abnormal weight gain		10	C
Cachexia		1	C
Feeding disorder		41	C
Food aversion		7	C
Malnutrition		1	C
Neonatal insufficient breast milk syndrome		4	C
Overweight		1	(
Poor feeding infant		7	(
Weight loss poor		2	C
Hyperglycaemic conditions NEC			
Hyperglycaemia		58	C

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

	DRA Version: MedDRA 24.0	
Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Insulin resistance	4	(
Hypoglycaemic conditions NEC		
Glycopenia	1	(
Hypoglycaemia	66	(
Hypoglycaemia unawareness	1	(
Postprandial hypoglycaemia	1	0
Iron deficiencies		
Iron deficiency	9	0
Iron excess		
Haemochromatosis	1	(
Iron overload	1	0
Lipid metabolism and deposit disorders NEC		
Body fat disorder	1	0
Metabolic acidoses (excl diabetic acidoses)		
Ketoacidosis	4	0
Lactic acidosis	1	(
Metabolic acidosis	2	0
Mixed acid-base disorders		
Acidosis	3	0
Potassium imbalance		
Hyperkalaemia	2	0
Hypokalaemia	3	(
Hypokalaemic syndrome	1	0
Sodium imbalance		
Hyponatraemia	6	(
Hyponatraemic syndrome	3	
Sugar intolerance (excl glucose intolerance)		
Lactose intolerance	1	
Total fluid volume decreased		
Dehydration	121	
Total fluid volume increased		
Fluid retention	35	
Hypervolaemia	1	(
Vitamin deficiencies NEC		
Hypovitaminosis	3	
Water soluble vitamin deficiencies		
Folate deficiency	2	
Vitamin B12 deficiency		
Metabolic disorders SOC TOTAL	1472	

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Reaction Name	-	Total	Fatal
Muscle & tissue disorders			
Arthropathies NEC			
Arthritis		170	0
Arthropathy		20	0
Autoimmune arthritis		4	0
Haemarthrosis		5	0
Joint microhaemorrhage		1	0
Palindromic rheumatism		1	0
Polyarthritis		13	0
Rheumatic fever		1	0
Sacroiliitis		3	0
Seronegative arthritis		2	0
Bone disorders NEC		-	Ŭ
Jaw disorder		3	0
Medial tibial stress syndrome		3	0
Osteitis		3	0
Osteonecrosis of jaw		2	0
Spinal disorder		1	0
Bone related signs and symptoms		1	0
Bone pain		246	0
Bone swelling		4	0
Coccydynia		4	0
Metatarsalgia		1	0
Pain in jaw		237	
Pubic pain		237	0
Spinal pain		41	0
Bursal disorders		41	0
Bursitis		43	0
Cartilage disorders		43	0
Chondritis		1	0
Costochondritis		39	0
Osteochondritis		1	0
Polychondritis		2	0
Connective tissue disorders NEC		2	0
Connective tissue disorder		1	0
		40	0
Polymyalgia rheumatica Reynold's syndrome		40	0
Sjogren's syndrome		4	0
Crystal arthropathic disorders		4	0
Chondrocalcinosis pyrophosphate		1	0
Crystal arthropathy		1	0
Epiphyseal disorders		1	U
Epiphysear disorders Epiphyses premature fusion		1	0
		1	U
Extremity deformities		1	0
Bone deformity			0
Finger deformity		1	0
Foot deformity			
Hand deformity		2	
Knee deformity		1	(
Limb deformity		4	(
Musculoskeletal deformity		1	C
Intervertebral disc disorders NEC			
Intervertebral disc protrusion		1	C
Joint related disorders NEC			

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Reaction Name		Total	Fatal
Muscle & tissue disoldersle & tissue disord	ders cont'd		
Chondromalacia		1	C
Joint deposit		1	0
Joint destruction		1	0
Joint laxity		3	0
Joint lock		16	0
Patellofemoral pain syndrome		1	0
Periarthritis		92	0
Rotator cuff syndrome		8	0
Temporomandibular joint syndrome		7	0
Joint related signs and symptoms			
Arthralgia		6001	0
Jaw clicking		4	0
Joint effusion		12	0
Joint noise		20	0
Joint range of motion decreased		11	0
Joint stiffness		154	0
Joint swelling		317	0
Joint vibration		1	0
Joint warmth		11	0
Loose body in joint		1	0
Ligament disorders			
Symphysiolysis		1	0
Lupus erythematosus (incl subtypes)			Ŭ
Lupus-like syndrome		1	0
Systemic lupus erythematosus		15	0
Metabolic bone disorders		.0	Ŭ
Osteopenia		1	0
Osteoporosis		1	0
Muscle infections and inflammations			Ŭ
Antisynthetase syndrome		2	0
Myositis		17	0
Polymyositis		4	0
Muscle pains			Ŭ
Fibromyalgia		68	0
Myalgia		7644	0
Myalgia intercostal		1	0
Myofascial pain syndrome		6	0
Muscle related signs and symptoms N	EC	Ű	Ŭ
Haematoma muscle		1	0
Muscle atrophy		13	0
Muscle discomfort		2	0
Muscle disorder		3	0
Muscle fatigue		242	0
Muscle haemorrhage		1	C
Muscle mass		3	C
Muscle oedema		1	C
Muscle spasms		1102	C
Muscle spasms Muscle swelling		17	C
Muscle tightness		54	C
Muscle twitching		260	C
Muscle tone abnormalities		200	U
Muscle rigidity		11	C
Nuchal rigidity		10	

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 2		
Reaction Name	Total	Fatal
Muscle & tissue disorders le & tissue disorders cont'd		
Torticollis	3	0
Trismus	24	0
Muscle weakness conditions		
Muscular weakness	566	0
Musculoskeletal and connective tissue conditions NEC		
Back disorder	1	0
Growth disorder	1	0
Limb mass	11	0
Mandibular mass	2	0
Mastication disorder	3	
Mobility decreased	54	0
Musculoskeletal disorder	10	
Musculoskeletal stiffness	831	0
Posture abnormal	1	0
Weight bearing difficulty	1	0
Musculoskeletal and connective tissue deformities of skull, face and		
buccal cavity		
Head deformity	2	0
Musculoskeletal and connective tissue infections and inflammations I		-
Dactylitis	2	0
Dupuytren's contracture	1	0
Fasciitis	1	0
Plantar fasciitis	5	
Musculoskeletal and connective tissue pain and discomfort		
Back pain	1509	0
Flank pain	31	0
Limb discomfort	1015	
Musculoskeletal chest pain	126	
Musculoskeletal discomfort	64	
Musculoskeletal pain	33	
Neck pain	1209	
Pain in extremity	8428	
Rheumatic disorder	8	
Myopathies	Ŭ	
Myopathy	4	0
Rhabdomyolysis	6	0
Osteoarthropathies	0	
Nodal osteoarthritis	1	0
Osteoarthritis	28	
Spinal osteoarthritis	1	0
Psoriatic arthropathies		
Psoriatic arthropathy	12	0
Rheumatoid arthropathies	12	
Rheumatoid arthritis	80	0
Soft tissue disorders NEC	00	
Axillary mass	167	0
Fluctuance	107	0
Groin pain	77	
Neck mass	18	-
	10	-
Purple glove syndrome Soft tissue disorder	2	
	3	0
Soft tissue swelling	3	0
Spine and neck deformities		

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Reaction Name	Total	Fatal
Muscle & tissue disorders e & tissue disorders cont'd		
Kyphosis	2	0
Lordosis	1	0
Neck deformity	1	0
Scoliosis	1	0
Spondyloarthropathies		
Ankylosing spondylitis	6	0
Arthritis reactive	26	0
Spondylitis	1	0
Synovial disorders		
Synovial cyst	15	0
Synovitis	4	0
Tendon disorders		
Enthesopathy	1	0
Tendon disorder	2	0
Tendon pain	14	0
Tendonitis	21	0
Tenosynovitis	2	0
Tenosynovitis stenosans	2	0
Trigger finger	17	0
Trunk deformities		
Drooping shoulder syndrome	1	0
Muscle & tissue disorders SOC TOTAL	31516	0

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968 MedDRA Ver Reaction Name	sion: MedDRA 24.0 Total	Fatal
Neoplasms	Total	raial
B-cell lymphomas NEC		
Follicular lymphoma	3	C
Bone neoplasms unspecified malignancy		
Bone neoplasm	1	0
		0
Breast and nipple neoplasms benign Benign breast neoplasm	1	0
		0
Breast and nipple neoplasms malignant Breast cancer	27	0
Breast cancer female	21	0
Breast cancer male	1	0
	1	0
Breast cancer stage I	1	0
Breast cancer stage III Invasive ductal breast carcinoma	1	
	2	0
Triple negative breast cancer	2	0
Cardiovascular neoplasms benign	1	
Pericardial lipoma		0
Colorectal neoplasms malignant Colon cancer	1	
	1	0
Colorectal cancer		
Rectal cancer		0
Endocrine neoplasms malignant and unspecified NEC		
Thyroid neoplasm	1	0
Endometrial neoplasms malignant		
Endometrial cancer	2	0
Follicular lymphomas		
Primary gastrointestinal follicular lymphoma	1	0
Gastric neoplasms malignant		
	1	1
Gastrointestinal neoplasms malignant NEC		
Gastrointestinal carcinoma	3	0
Hodgkin's disease NEC		
Hodgkin's disease	2	0
Islet cell neoplasms and APUDoma NEC		
Pancreatic neuroendocrine tumour	1	0
Leukaemias acute NEC		
Acute leukaemia	1	0
Leukaemias chronic lymphocytic		
Chronic lymphocytic leukaemia	2	0
Lip and oral cavity neoplasms malignant		
Lip and/or oral cavity cancer recurrent	1	0
Lymphomas unspecified NEC	10	
Lymphoma	16	1
Metastases to specified sites		
Metastases to liver	1	0
Metastases to lymph nodes	5	0
Metastases to unknown and unspecified sites		-
Metastasis	1	0
Myelodysplastic syndromes		
Myelodysplastic syndrome	2	0
Myeloproliferative disorders (excl leukaemias)		
Essential thrombocythaemia	1	C
Neoplasms benign site unspecified NEC		
Adenoma benign	1	0

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 24.0		
Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Neoplasms malignant site unspecified NEC		
Adenocarcinoma metastatic	1	0
Neoplasm malignant	4	0
Second primary malignancy	1	0
Squamous cell carcinoma	3	
Neoplasms unspecified malignancy and site unspecified NEC		_
Neoplasm	1	0
Neoplasm recurrence	1	0
Nervous system neoplasms benign NEC		Ű
Cranial nerve neoplasm benign	1	0
Neurilemmoma benign	1	0
Nervous system neoplasms unspecified malignancy NEC		
Brain neoplasm	1	0
Neuromas		
Acoustic neuroma	1	0
Non-Hodgkin's lymphomas NEC		
Non-Hodgkin's lymphoma	2	0
Oesophageal neoplasms malignant	2	
Oesophageal cancer metastatic	4	0
	4	0
Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified		
Tonsil cancer	2	0
Pancreatic neoplasms malignant (excl islet cell and carcinoid)	2	
Pancreatic carcinoma	4	0
Plasma cell myelomas		
POEMS syndrome	1	0
Plasma cell myeloma	1	0
Plasma cell neoplasms NEC	1	
TEMPI syndrome	1	0
Prostatic neoplasms malignant	1	
Prostate cancer	3	0
Renal neoplasms malignant	5	
Renal cancer	2	0
Respiratory tract and pleural neoplasms malignant cell type unspecified	2	
NEC		
Bronchial carcinoma	1	0
Lung neoplasm malignant	6	0
Skin melanomas (excl ocular)	Ŭ	
Malignant melanoma	1	0
Skin neoplasms benign		Ŭ
Acrochordon	2	0
Anogenital warts	4	
Haemangioma of skin	3	
Melanocytic naevus	4	0
Skin papilloma	4	
		0
Skin neoplasms malignant and unspecified (excl melanoma) Basal cell carcinoma	2	
	2	0
Bowen's disease	1	
Neoplasm skin	1	0
Squamous cell carcinoma of skin	1	0
Soft tissue neoplasms benign NEC		
Lipoma	4	0
Lymphangioma	1	0

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Lanics Reaction Date. 10-Apr-1000			
Reaction Name		Total	Fatal
Neoplasms Neoplasms c	ont'd		
Soft tissue sarcomas histology	unspecified		
Sarcoma		1	0
Thyroid neoplasms malignant			
Papillary thyroid cancer		2	0
Thyroid cancer		1	0
Uterine neoplasms benign			
Uterine leiomyoma		7	0
Neoplasms SOC TOTAL		169	2

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Reaction Name	Total	Fatal
Nervous system disorders		
Abnormal reflexes		
Areflexia	4	0
Extensor plantar response	1	0
Hyperreflexia	2	0
Hyporeflexia	7	0
Abnormal sleep-related events		
Sleep paralysis	16	0
Absence seizures		
Petit mal epilepsy	20	0
Acute polyneuropathies		
Guillain-Barre syndrome	44	2
Subacute inflammatory demyelinating polyneuropathy	1	0
Autonomic nervous system disorders		
Anticholinergic syndrome	1	0
Autonomic nervous system imbalance	6	0
Autonomic neuropathy	1	0
Horner's syndrome	1	0
Central nervous system aneurysms and dissections		
Intracranial aneurysm	2	1
Vertebral artery dissection	1	0
Central nervous system haemorrhages and cerebrovascular accidents		
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	34	7
Cerebral infarction	23	1
Cerebral thrombosis	7	0
Cerebrovascular accident	289	
Embolic stroke	6	0
Haemorrhage intracranial	9	2
Haemorrhagic cerebral infarction	1	0
Haemorrhagic stroke	8	3
Internal capsule infarction	1	C
Intracranial haematoma	1	C
Ischaemic cerebral infarction	1	0
Ischaemic stroke	31	1
Lacunar infarction	2	C
Lacunar stroke	2	C
Lateral medullary syndrome	1	C
Subarachnoid haemorrhage	12	5
Thalamic infarction	1	C
Thrombotic stroke	2	C
Central nervous system inflammatory disorders NEC		
Gliosis	1	0
Central nervous system vascular disorders NEC		
Brain hypoxia	1	1

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968	MedDRA Version: MedDRA 24.0		
Reaction Name		<u>Total</u>	Fatal
Nervous system disorders us system disorders co	ont'd		
Central nervous system vasculitis		1	0
Cerebral congestion		1	0
Cerebral small vessel ischaemic disease		1	0
Cerebrovascular disorder		1	0
Reversible cerebral vasoconstriction syndr	ome	1	0
Cerebrovascular venous and sinus thrombos	sis		
Cerebral venous sinus thrombosis		31	2
Cerebral venous thrombosis		4	0
Superior sagittal sinus thrombosis		3	0
Transverse sinus thrombosis		1	0
Cervical spinal cord and nerve root disorders	S		
Cervicobrachial syndrome		3	0
Choreiform movements			
Chorea		2	0
Chronic polyneuropathies			
Demyelinating polyneuropathy		1	0
Coma states			
Coma		7	0
Diabetic coma		1	0
Hypoglycaemic coma		1	0
Coordination and balance disturbances			
Ataxia		7	0
Balance disorder		246	0
Coordination abnormal		33	0
Dysdiadochokinesis		1	0
Dysstasia		34	0
Nystagmus		9	0
Cortical dysfunction NEC			
Aphasia		48	0
Apraxia		1	0
Dyspraxia		1	0
Neurologic neglect syndrome		1	0
Sensory processing disorder		2	0
Visuospatial deficit		1	0
Cranial nerve disorders NEC			
Cranial nerve disorder		2	0
Dementia (excl Alzheimer's type)			
Dementia		10	0
Dementia with Lewy bodies		1	0
Senile dementia		1	0
Demyelinating disorders NEC			
Acute disseminated encephalomyelitis		4	0
Clinically isolated syndrome		1	0
Demyelination		7	0
Neuromyelitis optica spectrum disorder		1	0
Disturbances in consciousness NEC			
Altered state of consciousness		9	0
Consciousness fluctuating		2	0
Depressed level of consciousness		33	1
Lethargy		1602	0
Loss of consciousness		382	C
Sedation		6	C
Somnolence		678	0

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968	MedDRA Version: MedDRA 24.0		
Reaction Name		<u>Total</u>	Fatal
Nervous system disordersus system disorders c	ont'd		
Stupor		3	0
Syncope		1321	0
Disturbances in sleep phase rhythm			
Irregular sleep phase		1	0
Irregular sleep wake rhythm disorder		1	0
Dyskinesias and movement disorders NEC			-
Akathisia		3	0
Bradykinesia		10	0
Clumsiness		13	0
Dyskinesia		46	0
Extrapyramidal disorder		2	0
Fine motor skill dysfunction		7	0
Foetal movement disorder		1	0
Hyperkinesia		3	0
Hypokinesia		40	0
Motor dysfunction		2	0
Movement disorder		35	0
		17	0
Psychomotor hyperactivity		1	0
Synkinesis Tardiya dyakinasia		1	0
Tardive dyskinesia		2	0
Dystonias			0
Dystonia		14	0
Writer's cramp		1	0
Encephalitis NEC			
Encephalitis autoimmune		1	0
Limbic encephalitis		1	0
Noninfective encephalitis		2	0
Encephalopathies NEC		-	
Encephalopathy		3	0
Hashimoto's encephalopathy		1	0
Posterior reversible encephalopathy syndr	ome	1	0
Eye movement disorders			
IIIrd nerve disorder		1	0
Illrd nerve paralysis		5	0
IVth nerve paralysis		1	0
Microvascular cranial nerve palsy		1	0
VIth nerve paralysis		8	0
Facial cranial nerve disorders			
Bell's palsy		325	0
Facial nerve disorder		6	0
Facial paralysis		265	0
Facial paresis		68	0
Facial spasm		30	0
Generalised tonic-clonic seizures			
Generalised tonic-clonic seizure		29	0
Headaches NEC			
Cervicogenic headache		3	0
Cluster headache		146	0
Cold-stimulus headache		12	0
Drug withdrawal headache		2	0
Exertional headache		7	0
External compression headache		1	0
Headache		18256	0

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968	MedDRA Version: MedDRA 24.0		
Reaction Name		Total	Fatal
Nervous system disorders us system disorders of	ont'd		
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	1	0
Sinus headache	county	253	0
Tension headache		382	0
Thunderclap headache		4	0
Vascular headache		12	0
Hydrocephalic conditions		12	0
Hydrocephalus		1	0
Hypoglossal nerve disorders		1	0
Tongue paralysis		1	0
Increased intracranial pressure disorders		1	0
Brain compression		1	0
Brain oedema		1	0
		4	-
Idiopathic intracranial hypertension		4	0 0
Intracranial pressure increased Intellectual disabilities		1	U
			0
Intellectual disability		2	0
Lumbar spinal cord and nerve root disorder	5	= 4	0
Sciatica		54	0
Memory loss (excl dementia)		400	0
Amnesia		100	0
Memory impairment		103	0
Transient global amnesia		(0
Mental impairment (excl dementia and men	lory loss)	= 0	
Cognitive disorder		53	0
Cognitive linguistic deficit		1	0
Disturbance in attention		200	0
Mental impairment		32	0
Migraine headaches			-
Hemiplegic migraine		16	0
Migraine		1878	0
Migraine with aura		131	0
Migraine without aura		13	0
Ophthalmic migraine		4	0
Retinal migraine		20	0
Typical aura without headache		5	0
Vestibular migraine		13	0
Mixed cranial nerve disorders			
Bulbar palsy		1	0
Mononeuropathies			
Carpal tunnel syndrome		15	0
Cubital tunnel syndrome		1	0
Meralgia paraesthetica		1	0
Mononeuropathy		1	0
Nerve compression		13	0
Peripheral nerve lesion		1	0
Peroneal nerve palsy		9	0
Sciatic nerve neuropathy		2	0
Ulnar neuritis		1	0

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

	MedDRA Version: MedDRA 24.0	Ectol
Reaction Name Nervous system disorders us system disorders con	nt'd Total	<u>Fatal</u>
Multiple sclerosis acute and progressive		
Band sensation	1	
Multiple sclerosis	23	
•	18	
Multiple sclerosis relapse		
Tumefactive multiple sclerosis <i>Muscle tone abnormal</i>		
	10	
Hypotonia Muscle tone disorder	13	
Serotonin syndrome		
Stiff leg syndrome		
Myelitis (incl infective)	22	
Myelitis transverse		2 0
Narcolepsy and hypersomnia		
Cataplexy	70	
Hypersomnia	70	
Narcolepsy	2	4 O
Nervous system disorders NEC		
Central nervous system lesion Cerebral disorder	2	
-		
Nervous system disorder	7	7 0
Neurologic visual problems NEC		
Hemianopia		
Hemianopia homonymous		
Quadrantanopia		
Tunnel vision	12	2 0
Neurological signs and symptoms NEC		
Clonus	3	
Decerebrate posture	6646	
Dizziness	6646	
Dizziness exertional	33	
Dizziness postural	528	
Drooling	16	
Fontanelle bulging	400	2 0
Head discomfort	199	
Hyporesponsive to stimuli		
Inability to crawl		
Infant irritability	6	
Myoclonus	17	
Neurological symptom	33	
Patient elopement		
Persistent postural-perceptual dizziness	11	
Presyncope	413	
Sensory overload	2	
Slow response to stimuli		
Tongue biting	3	
Unresponsive to stimuli	34	4 C
Neuromuscular disorders NEC		-
Muscle contractions involuntary	15	
Muscle spasticity	9	
Neuromuscular pain		3 0
Neuromuscular junction dysfunction		
Myasthenia gravis	3	
Myasthenia gravis crisis		2 0

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

	Total	Fatal
ont'd		
	161	0
	12	0
	165	0
	20	0
	5	0
	342	0
	2	0
	5	0
	30	0
	2	0
	1	0
	2	0
	59	0
		0
		0
		0
	1	0
	7	1
	31	0
		0
	1	0
	43	0
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	1	0
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	7	0
	3	0
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	ont'd i </td <td>ont'd 161 12 165 165 20 5 342 2 5 300 2 1 2 59 1840 2595 3 1 1 2 55 300 2 1 30 2 59 1 31 2595 3 31 255 1 43 46 82 33 6 1 1 43 46 82 3 3 6 1 7 3 6 1 7 3 6 1 7 3 6 1 7 3 6 1 7 3 7 3 7 3 7 3 7 3 <</td>	ont'd 161 12 165 165 20 5 342 2 5 300 2 1 2 59 1840 2595 3 1 1 2 55 300 2 1 30 2 59 1 31 2595 3 31 255 1 43 46 82 33 6 1 1 43 46 82 3 3 6 1 7 3 6 1 7 3 6 1 7 3 6 1 7 3 6 1 7 3 7 3 7 3 7 3 7 3 <

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968 Reaction Name		Total	Fatal
Nervous system disordersus system disorders	cont'd		
Convulsions local		1	0
Epilepsy		123	0
Epileptic aura		2	0
Epileptic encephalopathy		1	0
Febrile convulsion		14	0
Partial seizures		15	0
Post stroke seizure		1	0
Psychogenic seizure		7	0
Seizure		386	0
Seizure anoxic		1	0
Seizure cluster		4	0
Seizure like phenomena		1	0
Status epilepticus		34	0
Tonic clonic movements		2	0
Tonic convulsion		15	0
Tonic posturing		1	0
Sensory abnormalities NEC			
Ageusia		347	0
Allodynia		12	0
Aura		11	0
Complex regional pain syndrome		3	0
Dysgeusia		901	0
Electric shock sensation		22	0
Hypergeusia		1	0
Hypogeusia		3	0
Intercostal neuralgia		1	0
Loss of proprioception		3	0
Neuralgia		334	0
Persistent genital arousal disorder		1	0
Phantom limb syndrome		4	0
Post herpetic neuralgia		13	0
Restless arm syndrome		1	0
Restless legs syndrome		77	0
Sensory disturbance		54	0
Sensory loss		51	0
Taste disorder		189	0
Visual perseveration		1	0
Sleep disturbances NEC			
Sleep deficit		3	0
Sudden onset of sleep		1	0
Speech and language abnormalities			
Dysarthria		115	0
Incoherent		8	0
Language disorder		1	0
Repetitive speech		1	0
Slow speech		9	0
Speech disorder		39	0
Spinal cord and nerve root disorders NEC			
Radiculitis brachial		7	0
Radiculopathy		4	0
Structural brain disorders NEC			
Brain injury		4	2
Hyperintensity in brain deep nuclei		1	0

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Laniest Reaction Date. 13-Apr-1900			
Reaction Name		Total	Fatal
Nervous system disordersus system disorders	s cont'd		
Transient cerebrovascular events			
Transient ischaemic attack		111	1
Tremor (excl congenital)			
Action tremor		1	0
Essential tremor		3	0
Head titubation		8	0
Resting tremor		2	0
Tremor		1087	0
Trigeminal disorders			
Facial neuralgia		14	0
Numb chin syndrome		2	0
Trigeminal nerve disorder		1	0
Trigeminal neuralgia		31	0
Vagus nerve disorders			
Vocal cord paralysis		1	0
Vertigos NEC			
Vertigo CNS origin		1	0
Nervous system disorders SOC TOTAL		45672	45

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 24.0		
Reaction Name	Total	Fatal
Pregnancy conditions		
Abortions not specified as induced or spontaneous	-	
Abortion missed	2	0
Abortions spontaneous		
Abortion spontaneous	181	0
Abortion threatened	2	0
Amniotic fluid and cavity disorders of pregnancy NEC		
Amniorrhoea	1	0
Foetal complications NEC	-	
Foetal hypokinesia	3	0
Foetal growth complications		
Foetal growth restriction	2	0
Foetal position and presentation abnormalities		
High foetal head	1	0
Oblique presentation	1	0
Gestational age and weight conditions		
Premature baby	2	1
Haemorrhagic complications of pregnancy		
Haemorrhage in pregnancy	1	0
Premature separation of placenta	1	0
Subchorionic haematoma	1	0
Subchorionic haemorrhage	1	0
Labour onset and length abnormalities		
Premature delivery	1	0
Premature labour	1	0
Premature rupture of membranes	1	0
Threatened labour	1	0
Maternal complications of labour NEC		
Uterine contractions abnormal	1	0
Uterine hypertonus	5	0
Maternal complications of pregnancy NEC		
Decidual cast	3	0
Ectopic pregnancy	1	0
Morning sickness	8	0
Preterm premature rupture of membranes	2	0
Somatic symptom disorder of pregnancy	2	0
Newborn complications NEC		0
Neonatal disorder	1	0
Normal newborn status	4	0
Normal newborn	1	0
Normal pregnancy, labour and delivery	4	0
Live birth	1	0
Pregnancy	23	0
Placental abnormalities (excl neoplasms)	4	0
Placental disorder	1	0
Postpartum complications NEC	0	0
Postpartum haemorrhage	2	0
Pregnancy complicated by maternal disorders	0	0
Gestational diabetes	2	0
Stillbirth and foetal death		
Foetal death	2	2
Stillbirth	3	2
Unintended pregnancies		-
Pregnancy after post coital contraception	1	0

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

Report Run Date: 15-Jul-2021	
Earliest Reaction Date: 13-Apr-1968	

Earliest Reaction Date. 13-Apr-1908	MEUDRA VEISION. MEUDRA 24.0		
Reaction Name		Total	Fatal
Pregnancy conditions regnancy conditions cont'c	1		
Pregnancy on contraceptive		3	0
Pregnancy on oral contraceptive		1	0
Pregnancy with contraceptive device		1	0
Unintended pregnancy		1	0
Pregnancy conditions SOC TOTAL		268	5

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Reaction Name	Total	Fatal
Device issues NEC		
Device connection issue	1	0
Device failure	1	0
Device issue	2	0
Device malfunction events NEC		
Device infusion issue	1	0
Device pacing issue	1	0
Device stimulation issue	1	0
Oversensing	14	0
Thrombosis in device	7	0
Device physical property and chemical issues		
Device breakage	1	0
Device defective	7	0
Device kink	1	0
Needle issue	2	0
Product contamination and sterility issues		
Product contamination	9	0
Product contamination physical	2	0
Product physical issues		
Liquid product physical issue	7	0
Product odour abnormal	1	0
Product physical issue	2	0
Product taste abnormal	8	0
Product quality issues NEC		
Product complaint	1	0
Product origin unknown	6	0
Product supply and availability issues		
Product availability issue	1	0
null SOC TOTAL	76	0

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968 M Reaction Name	ledDRA Version: MedDRA 24.0 Total	Fatal
	iotai	
Psychiatric disorders Abnormal behaviour NEC		
Abnormal behaviour	10	
	16	
Behaviour disorder		
Breath holding	e	
Sexually inappropriate behaviour		0
Staring	Z	4 O
Adjustment disorders		
Adjustment disorder with depressed mood		2 0
Affect alterations NEC		
Affect lability	6	
Constricted affect	2	2 0
Flat affect	4	
Inappropriate affect	12	2 0
Amnestic symptoms		
Paramnesia		3 0
Anxiety symptoms		
Agitation	57	′ 0
Anxiety	486	6 0
Immunisation anxiety related reaction	1	0 0
Nervousness	118	3 0
Stress	51	0 0
Tension	24	l 0
Attention deficit and disruptive behaviour disor	ders	
Attention deficit hyperactivity disorder	3	3 0
Behaviour and socialisation disturbances		
Aggression	7	r 0
Aversion		0 0
Indifference	6	6 0
Paranoia	15	5 0
Personality change	3	
Social avoidant behaviour	ξ	5 0
Soliloquy		
Suspiciousness		0 0
Bipolar disorders		
, Bipolar I disorder		2 0
Bipolar disorder	4	l o
Cognitive and attention disorders and disturbal	nces NEC	
Daydreaming	6	s 0
Distractibility		0
Mental fatigue	150	
Communications disorders		
Communication disorder	4	l o
Mutism		2 0
Confusion and disorientation		
Confusional state	603	3 O
Disorientation	185	
Decreased physical activity levels		
Catatonia	1	0
Deliria		
Delirium	79	e o
		í U
Delusional symptoms		
Delusion	8	8 0
Depressive disorders		

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968	MedDRA Version: MedDRA 24.0	
Reaction Name	Total	Fatal
Psychiatric disordersPsychiatric disorders cont		
Agitated depression	3	C
Depression	202	2 C
Depression suicidal	6	c C
Major depression	5	
Mixed anxiety and depressive disorder	1	0
Dissociative states		
Depersonalisation/derealisation disorder	6	c c
Dissociation	21	
Dissociative amnesia	2	
Dissociative disorder	2	1
Disturbances in initiating and maintaining s		
Initial insomnia	16	6 O
Insomnia	835	
Middle insomnia	21	1
Terminal insomnia	23	
Dyssomnias	20	
	1	
Dyssomnia	133	0
Poor quality sleep	100	6 C
Eating disorders NEC		
Bulimia nervosa	1	0
Eating disorder	8	1
Selective eating disorder	1	0
Emotional and mood disturbances NEC		
Anger	22	
Dysphoria	2	-
Emotional disorder	38	
Emotional distress	31	
Emotional poverty	1	0
Euphoric mood	30	1
Frustration tolerance decreased	3	-
Irritability	133	1
Mood altered	34	0
Factitious disorders		
Factitious disorder	2	2 0
Fear symptoms and phobic disorders (incl	social phobia)	
Agoraphobia	1	-
Fear	Ģ	0
Fear of falling	3	0
Fear of injection	4	. C
Osmophobia	1	0
Phobia	1	C
Phonophobia	2	
Social anxiety disorder	1	C
Social fear	1	
Fluctuating mood symptoms		
Mood swings	76	c C
Hallucinations (excl sleep-related)		
Hallucination	133	
Hallucination, auditory	10	
Hallucination, olfactory	8	
Hallucination, tactile		
Hallucination, visual	20	1
Hallucinations, mixed	20	

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968	MedDRA Version: MedDRA 24.0	
Reaction Name	Total	<u>Fatal</u>
Psychiatric disordersPsychiatric disorders cont	d	
Increased physical activity levels		
Restlessness	103	8 0
Infancy, childhood and adolescence psych	iatric disorders NEC	
Social (pragmatic) communication disord	ler 1	0
Learning disorders		
Learning disability	1	0
Learning disorder	1	0
Mental disorders NEC		
Mental disorder	12	2 0
Mental status changes	1	0
Mood alterations with depressive symptom	ns	
Anhedonia	2	2 0
Decreased interest	7	0
Depressed mood	237	/ 0
Depressive symptom	1	0
Feeling of despair	3	8 0
Feelings of worthlessness	1	0
Negative thoughts	1	0
Sense of a foreshortened future	2	2 0
Tearfulness	27	/ 0
Mood alterations with manic symptoms		
Hypomania	2	2 0
Mania	8	8 0
Mood disorders NEC		
Apathy	19	0
Boredom	1	0
Laziness	1	0
Listless	13	8 0
Narcolepsy and associated conditions		
Hypnagogic hallucination	3	8 0
Hypnopompic hallucination	2	
Sleep attacks	3	8 0
Obsessive-compulsive disorders and symp	otoms	
Obsessive-compulsive symptom	1	0
Orgasmic disorders and disturbances		
Anorgasmia	3	8 0
Female orgasmic disorder	2	2 0
Orgasm abnormal	3	8 0
Orgasmic sensation decreased	1	0
Premature ejaculation	1	0
Panic attacks and disorders		
Panic attack	106	6 0
Panic disorder		8 0
Panic reaction	18	8 0
Parasomnias		
Abnormal dreams	127	0
Abnormal sleep-related event	1	0
Confusional arousal	1	0
Exploding head syndrome		0
Nightmare	137	0
Parasomnia		0
Sleep inertia		0
Sleep talking	3	

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 24.0 Reaction Name MedDRA Version: MedDRA 24.0	Total	Fatal
Psychiatric disorders ^P sychiatric disorders cont'd	Total	ralai
	12	
Sleep terror Somnambulism	12	0
Perception disturbances NEC	2	U
	44	0
Autoscopy	11	0
Deja vu	2	0
Derealisation	/	0
Flashback	2	0
Illusion	1	0
Near death experience	1	0
Personality disorders NEC		
Personality disorder	1	0
Pervasive developmental disorders NEC		
Autism spectrum disorder	1	0
Psychiatric elimination disorders		
Enuresis	16	0
Psychiatric symptoms NEC		
Hypervigilance	8	0
Psychiatric symptom	3	0
Psychological trauma	1	0
Trance	1	0
Psychotic disorder NEC		
Psychotic behaviour	1	0
Psychotic disorder	13	0
Schizophrenia NEC		
Schizophrenia	1	0
Sexual arousal disorders		
Disturbance in sexual arousal	2	0
Sexual desire disorders		
Libido decreased	5	0
Libido increased	3	0
Loss of libido	10	0
Sleep disorders NEC		Ŭ
Sleep disorder	131	0
Sleep disorder due to general medical condition, insomnia type	1	0
Somatic symptom disorders	1	
Conversion disorders	9	0
Habit cough	13	
Somatic symptom disorder	1	0
Vomiting psychogenic	1	0
Speech and language usage disturbances	1	U
Disorganised speech	1	0
	4	
Logorrhoea	2	C
Speech articulation and rhythm disturbances	45	0
Dysphemia	15	0
Lack of spontaneous speech		0
Pressure of speech	1	0
Stereotypies and automatisms		
Bruxism	9	0
Head banging	5	0
Stereotypy	1	0
Stress disorders		
Burnout syndrome	1	0
Post-traumatic stress disorder	2	0

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Reaction Name	Total	Fatal
Psychiatric disorders ^{Psychiatric} disorders cont'd		
Substance related and addictive disorders		
Alcohol problem	1	0
Alcoholic hangover	1	0
Alcoholism	2	0
Nicotine dependence	1	0
Suicidal and self-injurious behaviour		
Completed suicide	1	1
Intentional self-injury	6	0
Self-injurious ideation	2	0
Suicidal ideation	19	0
Suicide attempt	13	0
Suicide threat	1	0
Thinking disturbances		
Bradyphrenia	29	0
Intrusive thoughts	4	0
Morbid thoughts	1	0
Tachyphrenia	4	0
Thinking abnormal	14	0
Tic disorders		
Tic	7	0
Psychiatric disorders SOC TOTAL	5006	1

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968	MedDRA Version: MedDRA 24.0	– / ·
Reaction Name	Total	Fatal
Renal & urinary disorders		
Bladder and urethral symptoms		
Bladder discomfort		2 0
Bladder irritation		2 0
Bladder pain	17	
Dysuria	38	
Incontinence	20	
Lower urinary tract symptoms	1	2 0
Micturition disorder	· · · · · · · · · · · · · · · · · · ·	1 0
Micturition urgency	24	
Pollakiuria	78	
Urethral pain		4 0
Urge incontinence	· · · · · · · · · · · · · · · · · · ·	1 0
Urinary hesitation	· · · · · · · · · · · · · · · · · · ·	1 0
Urinary incontinence	42	
Urinary retention	30	
Urine flow decreased	8	3 0
Bladder disorders NEC		
Bladder disorder		5 0
Bladder fibrosis	· · · · · · · · · · · · · · · · · · ·	1 0
Urinary bladder haemorrhage	· · · · · · · · · · · · · · · · · · ·	1 0
Bladder infections and inflammations		
Cystitis interstitial		3 0
Genital and urinary tract disorders NEC		
Genitourinary symptom	· · · · · · · · · · · · · · · · · · ·	1 0
Urinary tract disorder		3 0
Glomerulonephritis and nephrotic syndrome)	
Glomerulonephritis	· · · · · · · · · · · · · · · · · · ·	1 0
Glomerulonephritis minimal lesion		4 0
Glomerulonephritis rapidly progressive	· · · · · · · · · · · · · · · · · · ·	1 0
IgA nephropathy	· · · · · · · · · · · · · · · · · · ·	1 0
Nephrotic syndrome	15	5 0
Myoneurogenic bladder disorders		
Bladder dysfunction	4	4 0
Hypertonic bladder		1 0
Hypotonic urinary bladder		1 0
Loss of bladder sensation		1 0
Neurogenic bladder		1 0
Nephritis NEC		
Lupus nephritis		1 0
Nephritis		2 0
Tubulointerstitial nephritis		1 0
Renal disorders NEC		
Renal disorder		4 1
Renal haemorrhage		1 0
Renal mass		1 0
Renal failure and impairment		
Acute kidney injury	34	4 2
Anuria		3 0
Chronic kidney disease		3 0
Oliguria		1 0
Renal failure	1;	
Renal impairment	14	
Renal injury		1 0

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 24.0		
Reaction Name	Total	Fatal
Renal & urinary disorders & urinary disorders cont'd		
Renal lithiasis		
Nephrolithiasis	5	0
Renal neoplasms		
Renal cyst	1	0
Renal obstructive disorders		
Hydronephrosis	1	0
Renal structural abnormalities and trauma		
Kidney small	1	0
Renal vascular and ischaemic conditions		
Renal infarct	1	0
Renal vasculitis	1	1
Structural and obstructive urethral disorders (excl congenital)		
Urethral stenosis	1	0
Ureteric disorders NEC		
Ureteric stenosis	1	0
Urinary abnormalities		
Albuminuria	1	0
Chromaturia	34	0
Haematuria	25	0
Proteinuria	6	0
Urine abnormality	8	0
Urine odour abnormal	5	0
Urinary tract signs and symptoms NEC		
Costovertebral angle tenderness	1	0
Cystitis-like symptom	1	0
Haemorrhage urinary tract	15	0
Nocturia	3	0
Polyuria	4	0
Renal colic	2	0
Renal pain	179	0
Urinary tract pain	2	0
Renal & urinary disorders SOC TOTAL	691	5

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968	MedDRA Version: MedDRA 24.0		Ect-1
Reaction Name	Tot	ai ₋	Fatal
Reproductive & breast disorders		-	
Benign and malignant breast neoplasms			
Breast cyst		8	0
Breast disorders NEC			-
Breast disorder		1	0
Breast enlargement		9	0
Breast mass		68	0
Gynaecomastia		2	0
Mastoptosis		1	0
Breast infections and inflammations			-
Breast inflammation		1	0
Nipple inflammation		1	0
Breast signs and symptoms			
Breast discharge		2	0
Breast discomfort		6	0
Breast engorgement		3	0
Breast haematoma		1	0
Breast oedema		4	0
Breast pain		343	0
Breast swelling		68	0
Breast tenderness		40	0
Nipple pain		22	0
Nipple swelling		3	0
Cervix disorders NEC		_	
Cervical dysplasia		2	0
Cervix disorder		1	0
Cervix haemorrhage uterine		2	0
Ectropion of cervix		2	0
Cervix neoplasms			
Cervical polyp		1	0
Erection and ejaculation conditions and disc	orders		
Ejaculation disorder		2	0
Ejaculation failure		2	0
Erectile dysfunction		30	0
Erection increased		2	0
Organic erectile dysfunction		5	0
Painful ejaculation		1	0
Fallopian tube and ovary infections and infla	ammations		
Noninfective oophoritis		1	0
Lactation disorders		_	
Breast milk discolouration		3	0
Breast milk odour abnormal		1	C
Galactorrhoea		5	0
Lactation disorder		3	0
Lactation puerperal increased		1	C
Suppressed lactation		12	C
Menopausal effects NEC			
Artificial menopause		1	C
Menopausal symptoms		11	(
Menopause delayed		1	(
Premature menopause		8	C
Menopausal effects on the genitourinary tra	ct		
Atrophic vulvovaginitis		1	C
Postmenopausal haemorrhage		117	C

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968	MedDRA Version: MedDRA 24.0	
Reaction Name	Total	Fatal
Reproductive & breastedisorders & breast dis	sorders cont'd	
Menstruation and uterine bleeding NEC		
Abnormal uterine bleeding	5	0
Dysmenorrhoea	1349	0
Intermenstrual bleeding	544	1
Menstrual discomfort	11	
Menstrual disorder	840	1
Menstruation irregular	1427	
Premenstrual dysphoric disorder	5	
Premenstrual headache	4	
Premenstrual pain	56	1
Premenstrual syndrome	63	
Withdrawal bleed		
Menstruation with decreased bleeding		
Amenorrhoea	285	0
Hypomenorrhoea	324	
Menstruation delayed	2332	
	75	
Oligomenorrhoea	/5	
Menstruation with increased bleeding	0770	
Heavy menstrual bleeding	2779	1
Menometrorrhagia	14	
Polymenorrhoea	353	0
Ovarian and fallopian tube cysts and neo		
Ovarian cyst	8	
Polycystic ovaries	21	0
Ovarian and fallopian tube disorders NEC	;	
Adnexal torsion	1	0
Hydrosalpinx	2	1
Ovarian haemorrhage	3	
Ovulation disorder	1	0
Ovulation pain	28	
Premature ovulation	4	. 0
Pelvis and broad ligament disorders NEC		
Adnexa uteri pain	25	1
Pelvic floor muscle weakness	1	0
Pelvic haemorrhage	9	0
Penile and scrotal infections and inflamma	ations	
Balanoposthitis	1	0
Penile disorders NEC (excl erection and e	ejaculation)	
Penile discomfort	1	0
Penile erythema	1	0
Penile haemorrhage	3	0
Penile size reduced	1	0
Penile swelling	4	. 0
Penis disorder	4	. 0
Prostate and seminal vesicles infections a	and inflammations	
Prostatitis	3	0
Prostatic signs, symptoms and disorders	NEC	
Prostatic pain	1	0
Prostatomegaly	3	
Reproductive tract disorders NEC (excl ne		l
Genital haemorrhage	12	c c
Genital lesion	1	
Genital ulceration	5	

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0		
Tota	<u>al</u> _	Fatal
rders cont'd		
tions NEC		
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Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Reaction Name	Total	Fatal
Reproductive & breast disorders & breast disorders cont'd		
Vaginal discharge	37	0
Vaginal odour	1	0
Vulval oedema	1	0
Vulvovaginal burning sensation	3	0
Vulvovaginal dryness	3	0
Vulvovaginal pain	15	0
Vulvovaginal pruritus	5	0
Vulvovaginal rash	1	0
Vulvovaginal swelling	1	0
Reproductive & breast disorders SOC TOTAL	12481	0

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968 Reaction Name	Total	Fatal
Respiratory disorders		
Breathing abnormalities		
Apnoea	4	4 C
Apnoeic attack		
Dyspnoea	2686	6 6
Dyspnoea at rest	7	
Dyspnoea exertional	23	3 1
Hyperventilation	32	
Hypopnoea	67	
Hypoventilation		
Irregular breathing	14	4 C
Mouth breathing	3	3 C
Nocturnal dyspnoea		
Orthopnoea	3	3 C
Respiration abnormal	34	4 C
Respiratory arrest	11	
Respiratory depression		
Respiratory distress	14	4 C
Sleep apnoea syndrome	7	
Tachyphoea	21	
Bronchial conditions NEC		
Bronchial secretion retention		
Bronchiectasis	11	
Bronchospasm and obstruction		
Asthma	223	3 C
Asthma late onset		<u>2</u> C
Bronchospasm	11	
Chronic obstructive pulmonary disease	14	l 1
Cough variant asthma	3	
Obstructive airways disorder	6	6 C
Reversible airways obstruction		
Wheezing	287	
Conditions associated with abnormal gas ex	change	
Asphyxia		
Cyanosis central		
Hyperoxia		
Hypoxia	22	2 1
Respiratory acidosis		<u>2</u> C
Coughing and associated symptoms		
Allergic cough	۷ ۵	4 C
Cough	1636	6 2
Cough decreased		<u>2</u> C
Haemoptysis	34	4 C
Productive cough	106	6 C
Sputum discoloured	4	4 C
Sputum increased		
Diaphragmatic disorders		
Diaphragm muscle weakness		
Laryngeal and adjacent sites disorders NEC neoplasms)	c (excl infections and	
Laryngeal disorder		
Reflux laryngitis		
Vocal cord disorder		
Laryngeal spasm, oedema and obstruction		

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968	MedDRA Version: MedDRA 24.0	
Reaction Name	<u>Total</u>	<u>Fatal</u>
Respiratory disorders Respiratory disorders cont	'd	
Epiglottic oedema		1 0
Laryngeal obstruction		1 0
Laryngeal oedema		1 0
Laryngospasm		1 0
Stridor	1:	
Lower respiratory tract inflammatory and in		
Alveolitis		1 0
Hypersensitivity pneumonitis		1 0
Pneumonia aspiration		7 5
Pneumonitis	2	
Pulmonary sarcoidosis		2 0
Lower respiratory tract signs and symptom	e i i i i i i i i i i i i i i i i i i i	
Hiccups	24	4 0
Increased bronchial secretion	20	1 0
		2 0
Lung opacity	1	
Pleuritic pain		
Pulmonary pain	6	
Rales		4 0
Respiratory fremitus		1 0
Nasal congestion and inflammations		
Nasal congestion	18	
Nasal inflammation		2 0
Rhinitis allergic	1	1 0
Nasal disorders NEC		
Epistaxis	65	
Intranasal hypoaesthesia		1 0
Intranasal paraesthesia		1 0
Nasal crusting		1 0
Nasal disorder		1 0
Nasal dryness	24	
Nasal mucosal discolouration		1 0
Nasal odour		6 0
Nasal oedema	·	4 0
Nasal polyps		1 0
Nasal pruritus		3 0
Neonatal hypoxic conditions		
Dry lung syndrome		1 0
Gasping syndrome		1 0
Infantile apnoea		1 0
Paranasal sinus disorders (excl infections a	and neoplasms)	
Allergic sinusitis		1 0
Paranasal sinus inflammation		1 0
Sinonasal obstruction		9 0
Sinus congestion	4	0 ס
Sinus disorder		5 0
Parenchymal lung disorders NEC		
Atelectasis		1 0
Combined pulmonary fibrosis and emphy	vsema	1 0
Emphysema		2 0
Interstitial lung disease		7 0
Lung consolidation		1 0
Lung infiltration		1 0
Pulmonary alveolar haemorrhage		1 0

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968	MedDRA Version: MedDRA 24.0	
Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Pulmonary cavitation		1 0
Pulmonary fibrosis		4 0
Pharyngeal disorders (excl infections and ne	oplasms)	
Pharyngeal erythema	, ,	7 0
Pharyngeal haemorrhage		2 0
Pharyngeal hypoaesthesia		7 0
Pharyngeal inflammation		4 0
Pharyngeal oedema		0 0
Pharyngeal paraesthesia		6 0
Pharyngeal swelling	17	
Pharyngeal ulceration		3 0
Tonsillar erythema		4 0
Tonsillar haemorrhage		1 0
Tonsillar hypertrophy	5	2 0
Tonsillar inflammation		3 0
Tonsillar ulcer		1 0
Tonsillolith		1 0
Pleural infections and inflammations		
Pleurisy	2	2 0
Pneumothorax and pleural effusions NEC		
Pleural effusion	1	6 0
Pneumothorax		6 0
Pneumothorax spontaneous		1 0
Pulmonary hypertensions		
Pulmonary hypertension		2 0
Pulmonary oedemas		2
Acute respiratory distress syndrome		2 1
Pulmonary congestion		8 0
Pulmonary oedema		6 1
Pulmonary thrombotic and embolic condition		Ĭ
Pulmonary embolism	30	2 19
Pulmonary infarction		3 0
Pulmonary thrombosis		4 1
Respiratory failures (excl neonatal)		
Acute respiratory failure		2 1
Respiratory failure		9 2
Respiratory signs and symptoms NEC		·
Allergic respiratory symptom		5 0
Diaphragmalgia		5 0
Nasal flaring		1 0
Painful respiration		6 0
Pleural rub		1 0
Respiratory symptom	1	1 0
Suffocation feeling		1 0
Respiratory tract disorders NEC		i i
Aspiration		3 2
Lung disorder		2 0
Pulmonary mass		4 0
Respiratory disorder		9 0
Respiratory tract congestion		2 0
Respiratory tract haemorrhage		1 0
Respiratory tract initiation Respiratory tract irritation		5 0
Respiratory tract inflammation		1 (

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968 Med	DRA Version: MedDRA 24.0	
Reaction Name	<u>Total</u>	Fatal
Respiratory disorders Respiratory disorders cont'd		
Respiratory tract oedema	3	0
Thoracic musculoskeletal disorders		
Respiratory muscle weakness	2	0
Tracheal disorders (excl infections and neoplasm	s)	
Tracheal pain	1	0
Upper respiratory tract neoplasms		
Tonsillar cyst	1	0
Upper respiratory tract signs and symptoms		
Aphonia	76	0
Catarrh	12	0
Choking	11	1
Choking sensation	3	0
Dry throat	124	0
Dysphonia	112	0
Increased upper airway secretion	4	0
Increased viscosity of upper respiratory secretion	on 22	0
Nasal discharge discolouration	2	0
Nasal discomfort	38	0
Nasal obstruction	2	0
Oropharyngeal blistering	9	0
Oropharyngeal discomfort	44	
Oropharyngeal pain	1977	0
Oropharyngeal plaque	2	0
Paranasal sinus discomfort	30	0
Rhinalgia	10	0
Rhinorrhoea	607	0
Sinus pain	142	0
Sneezing	252	0
Snoring	7	0
Throat clearing	7	0
Throat irritation	171	0
Throat tightness	190	0
Upper airway obstruction	2	0
Upper-airway cough syndrome	6	0
Yawning	15	0
Vascular pulmonary disorders NEC		
Acute chest syndrome	1	0
Respiratory disorders SOC TOTAL	11124	45

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968 Reaction Name	MedDRA Version: MedDRA 24.0 Total	Fatal
	iulai	<u> </u>
Skin disorders		
Acnes	00	
Acne	96	
Acne cystic		
Dermatitis acneiform		7 0
Alopecias	400	
Alopecia	129	
Alopecia areata	14	
Alopecia totalis		
Androgenetic alopecia		
Madarosis	1	1 O
Angioedemas		
Angioedema	143	
Circumoral swelling	1	0
Apocrine and eccrine gland disorders		
Anhidrosis	1	0
Cold sweat	494	4 O
Hidradenitis	1	0
Hyperhidrosis	1416	
Milia	1	I 0
Miliaria	62	
Night sweats	403	3 0
Bullous conditions		
Blister	317	7 0
Blister rupture	1	I 0
Blood blister	21	
Dermatitis bullous	10	0 0
Erythema multiforme	22	2 0
Fracture blisters	1	I 0
Pemphigoid	13	3 0
Pemphigus	5	5 0
Stevens-Johnson syndrome		3 0
Toxic epidermal necrolysis	2	2 1
Connective tissue disorders		
Dermatomyositis	4	4 O
Dermal and epidermal conditions NEC		
Acute febrile neutrophilic dermatosis	1	I 0
Dermatosis	1	0
Dry skin	150	0 0
Macule	4	4 O
Neutrophilic dermatosis	1	I 0
Pain of skin	179) C
Papule	68	3 C
Pathergy reaction	1	
Peau d'orange	2	2 C
Scab	14	4 C
Scar pain	11	I C
Sensitive skin	104	4 C
Skin burning sensation	156	
Skin degenerative disorder		
Skin discolouration	80	-
Skin discomfort		
Skin disorder		
Skin fissures		

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

	A Version: MedDRA 24.0	Entol
Reaction Name Skin disorders Skin disorders cont'd	Total	Fatal
Skin indentation	2	
Skin induration	3	
Skin lesion	30	1
Skin lesion inflammation	1	
Skin necrosis	1	
Skin odour abnormal	14	
Skin plaque	1	
Skin reaction	97	
Skin sensitisation	21	1
Skin swelling	57	
Skin texture abnormal	1	0
Skin tightness	21	0
Skin warm	207	
Skin weeping	6	-
Sticky skin	1	0
Target skin lesion	2	0
Transient acantholytic dermatosis	1	0
Yellow skin	14	0
Dermatitis and eczema		
Dermatitis	77	
Dermatitis allergic	160	1
Dermatitis atopic	21	0
Dermatitis contact	10	1
Dermatitis diaper	3	
Dyshidrotic eczema	15	
Eczema	173	
Eczema asteatotic		0
Eczema nummular	4	0
Eczema weeping	1	0
Perioral dermatitis	1	0
Seborrhoeic dermatitis	2	
Skin irritation	72	0
Dermatitis ascribed to specific agent		
Drug eruption	25	
Drug reaction with eosinophilia and systemic sym	ptoms 1	Ŭ Ŭ
Fixed eruption	1	0
Toxic skin eruption	1	0
Erythemas		
Erythema	1534	
Palmar erythema	4	0
Red man syndrome	1	0
Exfoliative conditions		
Dermatitis exfoliative	1	0
Dermatitis exfoliative generalised	3	
Exfoliative rash	12	0
Keratolysis exfoliativa acquired	2	C
Skin exfoliation	69	0
Granulomatous and deep cutaneous inflammatory	conditions	
Cutaneous sarcoidosis	1	C
Granuloma annulare	2	C
Hyperkeratoses		
Hyperkeratosis	1	0
Keratosis pilaris	3	

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968 M	MedDRA Version: MedDRA 24.0	Eatel
Reaction Name Skin disorders Skin disorders cont'd	Total	Fatal
Nail psoriasis	1	
Palmoplantar pustulosis		
Psoriasis	109	
Pustular psoriasis	2	2 C
Purpura and related conditions		
Henoch-Schonlein purpura	4	-
Petechiae	95	
Purpura	32	2 C
Pustular conditions		
Acute generalised exanthematous pustulosis	s 1	C
Rashes, eruptions and exanthems NEC		
Butterfly rash	3	C C
Rash	3828	
Rash erythematous	813	
Rash macular	352	1
Rash maculo-papular	45	
Rash morbilliform	31	1
Rash papular	244	
Rash pruritic	837	
Rash vesicular	46	
Systemic lupus erythematosus rash	5	i C
Rosaceas		
Rosacea	20	C
Scaly conditions		
Dandruff	4	
Pityriasis	16	C
Sebaceous gland disorders		
Seborrhoea	4	. C
Skin and subcutaneous conditions NEC		
Cutaneous symptom	4	. C
Reactive perforating collagenosis	1	C
Skin mass	13	C
Skin and subcutaneous tissue ulcerations		
Mucocutaneous ulceration	1	C
Scleroderma associated digital ulcer	1	C
Skin erosion	18	C
Skin ulcer	10	C
Skin cysts and polyps		
Dermal cyst	8	C
Skin dystrophies		
Keloid scar	2	c C
Skin wrinkling	2	2 C
Skin haemorrhages		
Haemorrhage subcutaneous	6	c C
Skin haemorrhage	g	c c
Skin hyperplasias and hypertrophies		
Skin hypertrophy	2	
Skin hypoplasias and atrophies		
Skin atrophy	1	
Skin striae	4	
Skin injuries and mechanical dermatoses		
Decubitus ulcer	2	c c
Needle track marks	2	

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin preneoplastic conditions NEC		
Actinic keratosis	· · · · · · · · · · · · · · · · · · ·	1 0
Skin vascular conditions NEC		
Skin oedema	· · · · · · · · · · · · · · · · · · ·	1 0
Skin vasculitides		
Cutaneous vasculitis		7 0
Vasculitic rash	1	5 0
Skin vasomotor conditions		
Livedo reticularis	18	B 0
Telangiectasia and related conditions		
Telangiectasia	· · · · · · · · · · · · · · · · · · ·	1 0
Urticarias		
Chronic spontaneous urticaria		3 0
Cold urticaria		2 0
Idiopathic urticaria	· · · · · · · · · · · · · · · · · · ·	1 0
Mechanical urticaria		4 0
Solar urticaria		2 0
Urticaria	1204	4 0
Urticaria cholinergic	· · · · · · · · · · · · · · · · · · ·	1 0
Urticaria chronic		3 0
Urticaria contact	· · · · · · · · · · · · · · · · · · ·	1 0
Urticaria papular		3 0
Urticaria thermal		4 0
Urticarial vasculitis		3 0
Skin disorders SOC TOTAL	1833	5 1

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 24.0 Reaction Name	Total	Fatal
Social circumstances		<u>i atai</u>
Age related issues		
Infant	1	C
Menopause	15	C
Postmenopause	2	C
Criminal activity	۷	
Verbal abuse	1	C
Dependents	1	L
Sick relative	2	C
Disability issues	۷	L L
Bedridden	17	C
Breast prosthesis user	3	C
Disability	1	C
Hearing disability	1	C
Housebound	1	C
Immobile	10	
		C
Impaired driving ability	2	C
Impaired work ability	18	C
Loss of personal independence in daily activities Physical disability	3	C
	8	C
Sight disability	0	C
Sitting disability	2	C
Walking disability <i>Economic circumstances</i>	۷ ک	Ľ
	1	C
High income Low income	1	C
		C
Employment issues Retirement		<u> </u>
Stress at work	3	C
		C
Family and partner issues	1	~
Bed sharing	1	C
Non-occupational and unspecified environmental problems	1	~
Flooding Water pollution	1	C
Water pollution	2	C
Pregnancy related circumstances	40	C
Breast feeding	12	v
Multigravida	1	C
Social issues NEC	0	
Hair dye user	2	C
Tobacco use		
Ex-tobacco user	1	(
Non-tobacco user	4	C
Social circumstances SOC TOTAL	125	

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 24.0	Tatal	Fatal
Reaction Name	Total	Fatal
Surgical & medical procedures		
Anaesthesia and allied procedures		
Local anaesthesia	1	0
Nerve block	3	0
Antiinfective therapies		
COVID-19 treatment	3	0
Arterial therapeutic procedures (excl aortic)		0
Splenic artery embolisation	1	0
Blood and blood product treatment		0
Transfusion	1	0
Breast therapeutic procedures NEC		0
Axillary lymphadenectomy	1	0
Mammoplasty	1	0
Bronchial and pulmonary therapeutic procedures	4	0
Airway secretion clearance therapy	1	0
Cardiac therapeutic procedures NEC		0
Cardiac operation	1	0
Contraceptive methods female		0
Contraception	1	0
Contraceptive implant	1	0
Oral contraception	1	0
Contraceptive methods male		0
Condom	1	0
Dietary and nutritional therapies	0	0
Medical diet	3	
Nothing by mouth order	5	0
Wheat-free diet	1	0
Fertility and fertilisation interventions female	4	0
Endometrial scratching	1	0
Gastrointestinal therapeutic procedures NEC	4	0
Intestinal anastomosis	1 11	0
Prophylaxis of nausea and vomiting	11	0
Gynaecological therapeutic procedures NEC	F	0
Menstrual cycle management	5	0
Haematological therapeutic procedures NEC	1	0
Anticoagulant therapy <i>Hernia repairs</i>	1	0
Hernia repair	1	0
Hormonal therapeutic procedures NEC	1	0
Hormone replacement therapy	1	0
Hormone therapy	6	0
Immunisations	0	0
COVID-19 immunisation	74	1
Immunisation	22	0
Joint therapeutic procedures	22	0
Joint surgery	1	0
Knee arthroplasty	1	0
Large intestine therapeutic procedures		0
Appendicectomy	2	0
Limb therapeutic procedures	۷	0
Limb inmobilisation	7	0
Linb initiobilisation Limb operation	5	0
	ວ	0
Lymphoid tissue therapeutic procedures	1	0
Lymphadenectomy	1	0

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Earliest Reaction Date: 13-Apr-1968 MedDRA Ver	rsion: MedDRA 24.0	
Reaction Name	<u> </u>	Fatal
Surgical & medical procedures cont'd		
Splenectomy	1	0
Mastectomies		
Breast conserving surgery	3	0
Nail therapeutic procedures		
Nail operation	2	0
Nervous system therapeutic procedures NEC		
Multiple sclerosis relapse prophylaxis	2	0
Orbit and globe therapeutic procedures		
Strabismus correction	1	0
Phototherapies		
UV light therapy	1	0
Prophylactic procedures NEC		
Anaphylaxis prophylaxis	2	0
Immune tolerance induction	1	0
Prophylaxis against transplant rejection	1	0
Reproductive system disorder prophylaxis	1	0
Psychiatric therapies		
Electroconvulsive therapy	1	0
Renal therapeutic procedures		
Dialysis	1	0
Respiratory tract therapeutic procedures NEC		
Asthma prophylaxis	2	0
Skin and subcutaneous tissue therapeutic procedures N		
Dermal filler injection	4	0
Small intestine therapeutic procedures		
lleostomy	1	0
Therapeutic procedures NEC		
Abscess drainage	1	0
Anaphylaxis treatment	4	0
Bed rest	2	0
Fatigue management	1	0
Hospitalisation	8	0
Injection	17	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	1	0
Product used for unknown indication	2	0
Therapeutic procedure	1	0
Therapy change	1	0
Tracheal therapeutic procedures		
Tracheostomy	1	0
Uterine therapeutic procedures		
Endometrial ablation	1	0
Surgical & medical procedures SOC TOTAL	237	

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA	Total	Fatal
Vascular disorders		
Accelerated and malignant hypertension		
Hypertensive crisis	9	0
Hypertensive urgency	1	0
Malignant hypertension	3	0
Aneurysms and dissections non-site specific		
Aneurysm	1	0
Artery dissection	1	0
Aortic aneurysms and dissections		
Acute aortic syndrome	1	0
Aortic aneurysm rupture	1	1
Aortic dissection	1	0
Aortic embolism and thrombosis		
Aortic embolus	5	0
Aortic thrombosis	1	0
Arterial infections and inflammations		
Arteritis	1	0
Giant cell arteritis	10	0
Blood pressure disorders NEC		
Blood pressure fluctuation	9	0
Labile blood pressure	3	0
Bruising, ecchymosis and purpura		
Achenbach syndrome	3	0
Circulatory collapse and shock		
CT hypotension complex	2	0
Circulatory collapse	48	0
Hypoperfusion	1	0
Neurogenic shock	20	0
Peripheral circulatory failure	5	0
Shock	14	0
Haemorrhages NEC		
Bloody discharge	9	0
Haematoma	32	0
Haemorrhage	588	2
Internal haemorrhage	6	0
Venous haemorrhage	1	0
Lymphangiopathies		-
Lymphangiopathy	1	0
Lymphocele	4	0
Lymphoedemas	100	
Lymphoedema	139	0
Non-site specific embolism and thrombosis		
Arterial thrombosis	3	0
Embolism	63	0
Embolism venous	3	0
Microembolism	1	0
Thrombosis	268	6
Venous thrombosis	4	0
Non-site specific necrosis and vascular insufficiency NEC		-
Arterial occlusive disease	2	0
Haemorrhagic infarction	1	0
Infarction	2	0
Ischaemia	6	0
Vasospasm	1	0

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Reaction Name	edDRA Version: MedDRA 24.0 Tota	1	Fatal
Vascular disorders Vascular disorders cont'd			i atai
Non-site specific vascular disorders NEC			
Capillary disorder		1	0
Superficial vein prominence		1	0
Vascular pain		13	0
Vasodilatation		24	0
Vein discolouration	2	5	0
Vein disorder		6	0
Vein rupture		3	0
Peripheral embolism and thrombosis		1	0
Axillary vein thrombosis		1	0
Blue toe syndrome		19	0
Deep vein thrombosis		37	0
Femoral artery embolism		1	0
Jugular vein thrombosis		2	0
Pelvic venous thrombosis		4	0
Peripheral embolism		1	0
Subclavian artery embolism		1	0
Subclavian vein thrombosis		2	0
Thrombophlebitis		16	0
Thrombophlebitis superficial		10	0
Peripheral vascular disorders NEC			0
Cyanosis		29	0
Erythromelalgia		1	0
Flushing	33	1	0
Hot flush		59	0
Peripheral vasoconstriction, necrosis and vaso		59	0
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	22		0
Peripheral ischaemia		11	0
Poor peripheral circulation		10	0
		16	0
Raynaud's phenomenon Vasoconstriction		2	0
Phlebitis NEC		4	0
Phlebitis		23	0
Phlebitis superficial		5	0
Site specific vascular disorders NEC		5	0
Inferior vena cava dilatation		1	0
Pallor	22	22	0
Varicose veins NEC			0
Spider vein		3	0
Varicophlebitis		2	0
Varicophieblis Varicose vein		2	0
		14	0
Vascular hypertensive disorders NEC		1	0
Diastolic hypertension		2	0
Essential hypertension		3	0
Hypertension	37	9	1
Labile hypertension		1	0
Orthostatic hypertension		1	0
Secondary hypertension		1	0

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

Report Run Date: 15-Jul-2021 Earliest Reaction Date: 13-Apr-1968

Reaction Name	Τ	<u>otal</u>	Fatal
Vascular disorders Vascular disorders cont'd			
Systolic hypertension		4	0
Vascular hypotensive disorders			
Hypotension		282	0
Orthostatic hypotension		22	0
Vasculitides NEC			
Behcet's syndrome		4	0
Diffuse vasculitis		1	0
Granulomatosis with polyangiitis		1	0
MAGIC syndrome		1	0
Vasculitis		38	0
Vena caval embolism and thrombosis			
Vena cava embolism		1	0
Vena cava thrombosis		1	0
Vascular disorders SOC TOTAL		4022	10
TOTAL REACTIONS FOR DRUG	2	56005	460
TOTAL REPORTS		91567	
TOTAL FATAL OUTCOME REPORTS			460