

## Case Series Drug Analysis Print

### Name: FOI 22/1092 COVID-19 mRNA Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 23-Nov-2022

Data Lock Date: 22-Nov-2022 18:30:03

Earliest Reaction Date: 27-Apr-2021

MedDRA Version: MedDRA 25.1

FOI 22/1092 COVID-19 mRNA Pfizer/BioNTech Vaccine Analysis Print: 22/11/2022  
All UK spontaneous suspected Adverse Drug Reaction (ADR) reports for the COVID-19 mRNA Pfizer/BioNTech vaccines up to and including

## Case Series Drug Analysis Print

### Name: FOI 22/1092 COVID-19 mRNA Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 23-Nov-2022  
Earliest Reaction Date: 27-Apr-2021

Data Lock Date: 22-Nov-2022 18:30:03  
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i>Anaemias haemolytic NEC</i>		
Haemolytic anaemia	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	7	0
Lymphadenitis	1	0
Lymphadenopathy	56	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	2	0
Thrombocytopenia	1	0
<b>Blood disorders SOC TOTAL</b>	<b>68</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 22/1092 COVID-19 mRNA Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 23-Nov-2022  
Earliest Reaction Date: 27-Apr-2021

Data Lock Date: 22-Nov-2022 18:30:03  
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i>Cardiac disorders NEC</i>		
Cardiac ventricular thrombosis	1	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiovascular symptom	1	0
Palpitations	29	0
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	2	0
Myocardial infarction	2	1
<i>Myocardial disorders NEC</i>		
Dilatation ventricular	1	0
<i>Noninfectious myocarditis</i>		
Myocarditis	6	0
<i>Pericardial disorders NEC</i>		
Pericardial effusion	2	0
<i>Rate and rhythm disorders NEC</i>		
Cardiac flutter	1	0
Postural orthostatic tachycardia syndrome	2	0
Tachycardia	21	0
<b>Cardiac disorders SOC TOTAL</b>	<b>68</b>	<b>1</b>

# Case Series Drug Analysis Print

## Name: FOI 22/1092 COVID-19 mRNA Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 23-Nov-2022  
Earliest Reaction Date: 27-Apr-2021

Data Lock Date: 22-Nov-2022 18:30:03  
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Neurological disorders congenital NEC</i>		
Tourette's disorder	2	0
<b>Congenital disorders SOC TOTAL</b>	<b>2</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 22/1092 COVID-19 mRNA Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 23-Nov-2022  
Earliest Reaction Date: 27-Apr-2021

Data Lock Date: 22-Nov-2022 18:30:03  
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear disorder	1	0
Ear pain	4	0
<i>Hearing losses</i>		
Deafness	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	2	0
<b>Ear disorders SOC TOTAL</b>	<b>8</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 22/1092 COVID-19 mRNA Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 23-Nov-2022  
Earliest Reaction Date: 27-Apr-2021

Data Lock Date: 22-Nov-2022 18:30:03  
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i><b>Choroid and vitreous haemorrhages and vascular disorders</b></i>		
Vitreous haemorrhage	1	0
<i><b>Colour blindness (incl acquired)</b></i>		
Colour blindness acquired	1	0
Dyschromatopsia	1	0
<i><b>Lacrimation disorders</b></i>		
Lacrimation increased	1	0
<i><b>Lid, lash and lacrimal infections, irritations and inflammations</b></i>		
Eyelid irritation	1	0
Eyelid oedema	2	0
Swelling of eyelid	2	0
<i><b>Ocular disorders NEC</b></i>		
Eye pain	6	0
Eye swelling	6	0
<i><b>Ocular infections, inflammations and associated manifestations</b></i>		
Eye pruritus	1	0
<i><b>Ocular nerve and muscle disorders</b></i>		
Eye movement disorder	3	0
<i><b>Ocular sensation disorders</b></i>		
Asthenopia	1	0
Photophobia	2	0
<i><b>Pupil disorders</b></i>		
Mydriasis	1	0
<i><b>Retinal structural change, deposit and degeneration</b></i>		
Retinal detachment	1	0
<i><b>Visual colour distortions</b></i>		
Cyanopsia	1	0
<i><b>Visual disorders NEC</b></i>		
Diplopia	2	0
Vision blurred	4	0
<i><b>Visual impairment and blindness (excl colour blindness)</b></i>		
Blindness	3	0
Sudden visual loss	1	0
Visual impairment	4	0
<b>Eye disorders SOC TOTAL</b>	<b>45</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 22/1092 COVID-19 mRNA Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 23-Nov-2022  
Earliest Reaction Date: 27-Apr-2021

Data Lock Date: 22-Nov-2022 18:30:03  
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	35	0
Diarrhoea haemorrhagic	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	2	0
Flatulence	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	23	0
Abdominal pain lower	2	0
Abdominal pain upper	37	0
Gastrointestinal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	2	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	7	0
Dysphagia	1	0
<i>Nausea and vomiting symptoms</i>		
Cyclic vomiting syndrome	1	0
Nausea	84	0
Vomiting	128	0
Vomiting projectile	5	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematochezia	1	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	1	0
<i>Oral soft tissue disorders NEC</i>		
Cheilitis	1	0
Oral disorder	1	0
<i>Oral soft tissue signs and symptoms</i>		
Oral mucosal eruption	1	0
Oral mucosal erythema	1	0
Oral pain	2	0
Oral pruritus	1	0
Paraesthesia oral	3	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	10	0
<i>Salivary gland enlargements</i>		
Parotid gland enlargement	1	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	1	0
Mouth ulceration	1	0
<i>Tongue signs and symptoms</i>		
Glossodynia	2	0
Swollen tongue	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>358</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 22/1092 COVID-19 mRNA Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 23-Nov-2022  
Earliest Reaction Date: 27-Apr-2021

Data Lock Date: 22-Nov-2022 18:30:03  
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>General disorders</b>		
<i>Administration site reactions NEC</i>		
Puncture site pain	1	0
<i>Asthenic conditions</i>		
Asthenia	12	0
Fatigue	111	0
Malaise	45	0
<i>Febrile disorders</i>		
Pyrexia	146	0
<i>Feelings and sensations NEC</i>		
Chills	30	0
Feeling abnormal	5	0
Feeling cold	3	0
Feeling hot	10	0
Feeling jittery	1	0
Temperature intolerance	1	0
Thirst	1	0
<i>Gait disturbances</i>		
Gait disturbance	1	0
Gait inability	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	1	0
Crying	2	0
Illness	34	0
Influenza like illness	8	0
Peripheral swelling	27	0
Secretion discharge	1	0
Swelling	21	0
Swelling face	11	0
<i>Inflamations</i>		
Inflammation	4	0
<i>Injection site reactions</i>		
Injection site erythema	2	0
Injection site hypersensitivity	1	0
Injection site mass	1	0
Injection site pain	11	0
Injection site rash	1	0
Injection site swelling	1	0
<i>Oedema NEC</i>		
Oedema	1	0
<i>Pain and discomfort NEC</i>		
Axillary pain	32	0
Chest discomfort	7	0
Chest pain	35	0
Discomfort	1	0
Facial pain	1	0
Pain	22	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	14	0
Drug ineffective	3	0
No reaction on previous exposure to drug	1	0
<i>Vaccination site reactions</i>		
Extensive swelling of vaccinated limb	1	0



# Case Series Drug Analysis Print

## Name: FOI 22/1092 COVID-19 mRNA Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 23-Nov-2022  
Earliest Reaction Date: 27-Apr-2021

Data Lock Date: 22-Nov-2022 18:30:03  
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Vaccination site discomfort	1	0
Vaccination site erythema	3	0
Vaccination site haemorrhage	1	0
Vaccination site pain	19	0
Vaccination site rash	1	0
Vaccination site swelling	4	0
Vaccination site urticaria	1	0
<b>General disorders SOC TOTAL</b>	<b>642</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 22/1092 COVID-19 mRNA Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 23-Nov-2022  
Earliest Reaction Date: 27-Apr-2021

Data Lock Date: 22-Nov-2022 18:30:03  
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Allergic conditions NEC</i>		
Hypersensitivity	7	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	4	0
Anaphylactic shock	1	0
<i>Atopic disorders</i>		
Seasonal allergy	1	0
<i>Autoinflammatory diseases</i>		
Autoinflammatory disease	1	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	3	0
Multisystem inflammatory syndrome in children	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>18</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 22/1092 COVID-19 mRNA Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 23-Nov-2022  
Earliest Reaction Date: 27-Apr-2021

Data Lock Date: 22-Nov-2022 18:30:03  
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Infections</b>		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	1	0
<i>Bacterial infections NEC</i>		
Cellulitis	3	0
<i>Coronavirus infections</i>		
COVID-19	17	0
Post-acute COVID-19 syndrome	1	0
<i>Dental and oral soft tissue infections</i>		
Parotitis	1	0
<i>Ear infections</i>		
Labyrinthitis	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	3	0
<i>Herpes viral infections</i>		
Herpes zoster	13	0
Varicella	4	0
Varicella zoster virus infection	1	0
<i>Infections NEC</i>		
Infection	2	0
<i>Influenza viral infections</i>		
Influenza	4	0
<i>Mumps viral infections</i>		
Mumps	1	0
<i>Staphylococcal infections</i>		
Furuncle	1	0
<i>Trypanosomal infections</i>		
African trypanosomiasis	1	0
<i>Upper respiratory tract infections</i>		
Laryngitis	1	0
Nasopharyngitis	5	0
Tonsillitis	2	0
<i>Urinary tract infections</i>		
Urinary tract infection	1	0
<i>Vascular infections</i>		
Lymphangitis	1	0
<i>Viral infections NEC</i>		
Gastroenteritis viral	1	0
Gianotti-Crosti syndrome	1	0
Viral infection	1	0
Viral rash	1	0
<b>Infections SOC TOTAL</b>	<b>68</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 22/1092 COVID-19 mRNA Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 23-Nov-2022  
Earliest Reaction Date: 27-Apr-2021

Data Lock Date: 22-Nov-2022 18:30:03  
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Injuries</b>		
<i><b>Abdominal and gastrointestinal injuries NEC</b></i>		
Oral contusion	1	0
<i><b>Exposures associated with pregnancy, delivery and lactation</b></i>		
Foetal exposure during pregnancy	3	0
<i><b>Medication errors, product use errors and issues NEC</b></i>		
Medication error	3	0
Wrong dose	1	0
<i><b>Off label uses</b></i>		
Off label use	1	0
<i><b>Overdoses NEC</b></i>		
Overdose	1	0
<i><b>Product administration errors and issues</b></i>		
Inappropriate schedule of product administration	3	0
Product administered to patient of inappropriate age	2	0
<i><b>Skin injuries NEC</b></i>		
Contusion	5	0
<b>Injuries SOC TOTAL</b>	<b>20</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 22/1092 COVID-19 mRNA Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 23-Nov-2022  
Earliest Reaction Date: 27-Apr-2021

Data Lock Date: 22-Nov-2022 18:30:03  
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Investigations</b>		
<i><b>Blood gas and acid base analyses</b></i>		
Oxygen saturation	1	0
Oxygen saturation decreased	1	0
<i><b>Heart rate and pulse investigations</b></i>		
Carotid pulse abnormal	1	0
Heart rate	2	0
Heart rate increased	1	0
Heart rate irregular	2	0
<i><b>Immunology analyses NEC</b></i>		
Immunology test	1	0
<i><b>Investigations NEC</b></i>		
Polymerase chain reaction	1	0
<i><b>Neurologic diagnostic procedures</b></i>		
Sensory level	1	0
<i><b>Physical examination procedures and organ system status</b></i>		
Body temperature	8	0
Body temperature increased	10	0
Respiratory rate	1	0
Respiratory rate increased	1	0
<i><b>Skeletal and cardiac muscle analyses</b></i>		
Blood creatine phosphokinase increased	1	0
Troponin T increased	1	0
<i><b>Tissue enzyme analyses NEC</b></i>		
Blood lactate dehydrogenase increased	1	0
<i><b>Urinalysis NEC</b></i>		
Blood urine present	2	0
<i><b>Virus identification and serology</b></i>		
SARS-CoV-2 test	1	0
SARS-CoV-2 test positive	2	0
<b>Investigations SOC TOTAL</b>	<b>39</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 22/1092 COVID-19 mRNA Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 23-Nov-2022  
Earliest Reaction Date: 27-Apr-2021

Data Lock Date: 22-Nov-2022 18:30:03  
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i>Appetite disorders</i>		
Decreased appetite	19	0
Increased appetite	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Fulminant type 1 diabetes mellitus	1	0
<i>Total fluid volume decreased</i>		
Dehydration	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>22</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 22/1092 COVID-19 mRNA Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 23-Nov-2022  
Earliest Reaction Date: 27-Apr-2021

Data Lock Date: 22-Nov-2022 18:30:03  
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i><b>Arthropathies NEC</b></i>		
Arthritis	1	0
<i><b>Joint related signs and symptoms</b></i>		
Arthralgia	11	0
Joint swelling	3	0
<i><b>Muscle pains</b></i>		
Myalgia	22	0
<i><b>Muscle related signs and symptoms NEC</b></i>		
Muscle fatigue	1	0
Muscle spasms	5	0
Muscle twitching	2	0
<i><b>Muscle tone abnormalities</b></i>		
Muscle rigidity	2	0
<i><b>Muscle weakness conditions</b></i>		
Muscular weakness	2	0
<i><b>Musculoskeletal and connective tissue conditions NEC</b></i>		
Musculoskeletal stiffness	5	0
<i><b>Musculoskeletal and connective tissue pain and discomfort</b></i>		
Back pain	4	0
Limb discomfort	4	0
Musculoskeletal pain	1	0
Neck pain	5	0
Pain in extremity	66	0
<i><b>Soft tissue disorders NEC</b></i>		
Axillary mass	5	0
Groin pain	1	0
<i><b>Spondyloarthropathies</b></i>		
Arthritis reactive	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>141</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 22/1092 COVID-19 mRNA Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 23-Nov-2022  
Earliest Reaction Date: 27-Apr-2021

Data Lock Date: 22-Nov-2022 18:30:03  
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Absence seizures</i>		
Petit mal epilepsy	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebral haemorrhage	1	0
Cerebral infarction	1	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	1	1
<i>Coordination and balance disturbances</i>		
Balance disorder	3	0
<i>Cortical dysfunction NEC</i>		
Aphasia	1	0
<i>Demyelinating disorders NEC</i>		
Demyelination	1	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	18	0
Loss of consciousness	14	0
Somnolence	6	0
Syncope	55	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	1	0
Psychomotor hyperactivity	1	0
<i>Dystonias</i>		
Opisthotonus	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	4	0
Facial paralysis	3	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	4	0
<i>Headaches NEC</i>		
Cluster headache	2	0
Headache	179	0
Tension headache	2	0
<i>Increased intracranial pressure disorders</i>		
Intracranial pressure increased	1	0
<i>Memory loss (excl dementia)</i>		
Amnesia	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Disturbance in attention	1	0
Mental impairment	2	0
<i>Migraine headaches</i>		
Migraine	7	0
Migraine with aura	1	0
<i>Muscle tone abnormal</i>		
Hypotonia	1	0
<i>Myelitis (incl infective)</i>		
Myelitis transverse	1	0
<i>Narcolepsy and hypersomnia</i>		
Cataplexy	1	0
Narcolepsy	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	78	0
Dizziness postural	3	0



## Case Series Drug Analysis Print

### Name: FOI 22/1092 COVID-19 mRNA Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 23-Nov-2022  
Earliest Reaction Date: 27-Apr-2021

Data Lock Date: 22-Nov-2022 18:30:03  
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Drooling	1	0
Head discomfort	1	0
Presyncope	10	0
Tongue biting	1	0
Unresponsive to stimuli	2	0
<b>Olfactory nerve disorders</b>		
Anosmia	1	0
Parosmia	2	0
<b>Optic nerve disorders NEC</b>		
Optic neuritis	1	0
<b>Paraesthesias and dysaesthesias</b>		
Hypoaesthesia	3	0
Paraesthesia	5	0
<b>Paralysis and paresis (excl cranial nerve)</b>		
Hemiparesis	1	0
<b>Seizures and seizure disorders NEC</b>		
Atonic seizures	1	0
Epilepsy	3	0
Seizure	18	1
Status epilepticus	1	0
Tonic convulsion	3	0
<b>Sensory abnormalities NEC</b>		
Ageusia	3	0
Allodynia	1	0
Dysgeusia	1	0
Electric shock sensation	1	0
Neuralgia	2	0
Restless legs syndrome	1	0
Taste disorder	1	0
<b>Speech and language abnormalities</b>		
Dysarthria	3	0
Language disorder	1	0
Slow speech	1	0
<b>Tremor (excl congenital)</b>		
Tremor	8	0
<b>Nervous system disorders SOC TOTAL</b>	<b>474</b>	<b>2</b>

## Case Series Drug Analysis Print

### Name: FOI 22/1092 COVID-19 mRNA Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 23-Nov-2022  
Earliest Reaction Date: 27-Apr-2021

Data Lock Date: 22-Nov-2022 18:30:03  
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	1	0
<b><i>Adjustment disorders</i></b>		
Adjustment disorder	1	0
<b><i>Affect alterations NEC</i></b>		
Affect lability	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	2	0
Anxiety	6	0
Stress	1	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Aggression	1	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	7	0
Disorientation	3	0
<b><i>Deliria</i></b>		
Delirium	2	0
Delirium febrile	1	0
<b><i>Dissociative states</i></b>		
Depersonalisation/derealisation disorder	1	0
Dissociation	1	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Insomnia	5	0
<b><i>Dyssomnias</i></b>		
Poor quality sleep	1	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Emotional disorder	1	0
Irritability	1	0
Mood altered	1	0
<b><i>Fear symptoms and phobic disorders (incl social phobia)</i></b>		
Fear	1	0
<b><i>Hallucinations (excl sleep-related)</i></b>		
Hallucination	2	0
Hallucination, auditory	1	0
Hallucination, visual	1	0
<b><i>Increased physical activity levels</i></b>		
Restlessness	1	0
<b><i>Mood alterations with depressive symptoms</i></b>		
Tearfulness	1	0
<b><i>Panic attacks and disorders</i></b>		
Panic attack	1	0
<b><i>Parasomnias</i></b>		
Abnormal dreams	1	0
Nightmare	1	0
Parasomnia	2	0
Sleep terror	1	0
Somnambulism	1	0
<b><i>Psychiatric elimination disorders</i></b>		
Enuresis	1	0
<b><i>Sleep disorders NEC</i></b>		
Sleep disorder	1	0
<b><i>Stereotypies and automatisms</i></b>		

# Case Series Drug Analysis Print

## Name: FOI 22/1092 COVID-19 mRNA Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 23-Nov-2022  
Earliest Reaction Date: 27-Apr-2021

Data Lock Date: 22-Nov-2022 18:30:03  
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> Psychiatric disorders cont'd		
Head banging	1	0
<b><i>Tic disorders</i></b>		
Tic	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>55</b>	<b>0</b>

# Case Series Drug Analysis Print

## Name: FOI 22/1092 COVID-19 mRNA Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 23-Nov-2022  
Earliest Reaction Date: 27-Apr-2021

Data Lock Date: 22-Nov-2022 18:30:03  
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i>Bladder and urethral symptoms</i>		
Bladder pain	1	0
Urinary incontinence	1	0
<i>Renal failure and impairment</i>		
Renal impairment	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Renal pain	2	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>5</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 22/1092 COVID-19 mRNA Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 23-Nov-2022  
Earliest Reaction Date: 27-Apr-2021

Data Lock Date: 22-Nov-2022 18:30:03  
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Breast signs and symptoms</b></i>		
Breast swelling	2	0
<i><b>Erection and ejaculation conditions and disorders</b></i>		
Erectile dysfunction	1	0
<i><b>Menstruation and uterine bleeding NEC</b></i>		
Dysmenorrhoea	2	0
Intermenstrual bleeding	1	0
Menstrual disorder	4	0
Menstruation irregular	1	0
<i><b>Menstruation with decreased bleeding</b></i>		
Amenorrhoea	1	0
Hypomenorrhoea	1	0
Menstruation delayed	7	0
<i><b>Menstruation with increased bleeding</b></i>		
Heavy menstrual bleeding	5	0
<i><b>Scrotal disorders NEC</b></i>		
Scrotal pain	1	0
<i><b>Sexual function and fertility disorders NEC</b></i>		
Infertility	1	0
Infertility female	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>28</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 22/1092 COVID-19 mRNA Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 23-Nov-2022  
Earliest Reaction Date: 27-Apr-2021

Data Lock Date: 22-Nov-2022 18:30:03  
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Apnoea	1	0
Dyspnoea	34	0
Hyperventilation	2	0
Hypopnoea	1	0
Tachypnoea	1	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	2	0
Wheezing	2	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	22	0
Haemoptysis	2	0
<i><b>Lower respiratory tract signs and symptoms</b></i>		
Hiccups	1	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	2	0
Rhinitis allergic	1	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	24	0
<i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>		
Tonsillar hypertrophy	1	0
<i><b>Pneumothorax and pleural effusions NEC</b></i>		
Pleural effusion	1	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Aphonia	1	0
Dry throat	1	0
Dysphonia	2	0
Nasal discomfort	1	0
Oropharyngeal pain	21	0
Rhinorrhoea	7	0
Sneezing	4	0
Throat irritation	1	0
Throat tightness	2	0
<b>Respiratory disorders SOC TOTAL</b>	<b>137</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 22/1092 COVID-19 mRNA Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 23-Nov-2022  
Earliest Reaction Date: 27-Apr-2021

Data Lock Date: 22-Nov-2022 18:30:03  
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Alopecias</i></b>		
Alopecia	1	0
Alopecia areata	4	0
<b><i>Angioedemas</i></b>		
Angioedema	2	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Cold sweat	7	0
Hyperhidrosis	11	0
Night sweats	1	0
<b><i>Bullous conditions</i></b>		
Blister	6	0
<b><i>Dermal and epidermal conditions NEC</i></b>		
Dry skin	2	0
Pain of skin	2	0
Papule	1	0
Sensitive skin	1	0
Skin discolouration	1	0
Skin swelling	1	0
Skin warm	2	0
<b><i>Dermatitis and eczema</i></b>		
Dermatitis allergic	3	0
Eczema	4	0
Skin irritation	1	0
<b><i>Erythemas</i></b>		
Erythema	11	0
<b><i>Papulosquamous conditions</i></b>		
Pityriasis rosea	1	0
<b><i>Photosensitivity and photodermatosis conditions</i></b>		
Actinic prurigo	1	0
Photosensitivity reaction	1	0
<b><i>Pruritus NEC</i></b>		
Pruritus	26	0
<b><i>Psoriatic conditions</i></b>		
Psoriasis	3	0
<b><i>Purpura and related conditions</i></b>		
Henoch-Schonlein purpura	2	0
Petechiae	2	0
Purpura	3	0
<b><i>Rashes, eruptions and exanthems NEC</i></b>		
Butterfly rash	1	0
Rash	84	0
Rash erythematous	18	0
Rash macular	4	0
Rash maculo-papular	1	0
Rash morbilliform	1	0
Rash papular	8	0
Rash pruritic	10	0
Rash vesicular	5	0
<b><i>Urticarias</i></b>		
Solar urticaria	1	0
Urticaria	28	0
<b>Skin disorders SOC TOTAL</b>	<b>261</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 22/1092 COVID-19 mRNA Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 23-Nov-2022  
Earliest Reaction Date: 27-Apr-2021

Data Lock Date: 22-Nov-2022 18:30:03  
MedDRA Version: MedDRA 25.1

<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Social circumstances</b>		
<i>Age related issues</i>		
Menarche	1	0
<i>Dependents</i>		
Sick relative	3	0
<i>Dietary and nutritional issues</i>		
Feeding tube user	1	0
<i>Disability issues</i>		
Wheelchair user	1	0
<b>Social circumstances SOC TOTAL</b>	<b>6</b>	<b>0</b>



## Case Series Drug Analysis Print

### Name: FOI 22/1092 COVID-19 mRNA Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 23-Nov-2022  
Earliest Reaction Date: 27-Apr-2021

Data Lock Date: 22-Nov-2022 18:30:03  
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Immunisations</i>		
Immunisation	1	0
<i>Large intestine therapeutic procedures</i>		
Appendectomy	1	0
<i>Therapeutic procedures NEC</i>		
Interchange of vaccine products	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>3</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 22/1092 COVID-19 mRNA Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 23-Nov-2022  
Earliest Reaction Date: 27-Apr-2021

Data Lock Date: 22-Nov-2022 18:30:03  
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i>Circulatory collapse and shock</i>		
Shock	1	0
<i>Haemorrhages NEC</i>		
Haemorrhage	3	0
<i>Lymphoedemas</i>		
Lymphoedema	1	0
<i>Peripheral embolism and thrombosis</i>		
Blue toe syndrome	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	3	0
Flushing	4	0
Hot flush	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	23	0
<i>Varicose veins NEC</i>		
Varicose vein	1	0
<i>Vascular hypotensive disorders</i>		
Hypotension	5	0
<b>Vascular disorders SOC TOTAL</b>	<b>44</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>2512</b>	<b>3</b>
<b>TOTAL REPORTS</b>	<b>1026</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>3</b>