

## Case Series Drug Analysis Print

**Name: FOI 24/197 All Yellow Card reports for COVID-19 Pfizer-BioNTech vaccine (Batch EL0141)**

Report Run Date: 15-Mar-2024  
Data Lock Date: 13-Mar-2024 18:30:03  
Earliest Reaction Date: 07-Jan-2020  
MedDRA Version: MedDRA 26.1

FOI 24/197 All Yellow Card reports for COVID-19 Pfizer-BioNTech vaccine (Batch EL0141): FOI 24/197 All UK spontaneous Yellow card reports for COVID-19 Pfizer-BioNTech vaccine (batch EL0141) received up until 08/03/2023

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i>Anaemia deficiencies</i>		
Iron deficiency anaemia	1	0
<i>Anaemias NEC</i>		
Anaemia	1	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	2	0
<i>Coagulopathies</i>		
Coagulopathy	1	0
Thrombotic microangiopathy	1	0
<i>Leukopenias NEC</i>		
Lymphopenia	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	21	0
Lymphadenitis	3	0
Lymphadenopathy	134	0
Necrotic lymphadenopathy	1	0
<i>Marrow depression and hypoplastic anaemias</i>		
Aplastic anaemia	1	0
Pancytopenia	1	0
<i>Neutropenias</i>		
Neutropenia	1	0
<i>Platelet disorders NEC</i>		
Platelet disorder	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	2	0
Thrombocytopenia	4	0
Thrombotic thrombocytopenic purpura	1	0
<b>Blood disorders SOC TOTAL</b>	<b>177</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i><b>Cardiac disorders NEC</b></i>		
Cardiac disorder	2	1
Intracardiac thrombus	1	0
<i><b>Cardiac signs and symptoms NEC</b></i>		
Palpitations	43	0
<i><b>Coronary artery disorders NEC</b></i>		
Coronary artery disease	1	1
<i><b>Heart failures NEC</b></i>		
Cardiac failure	1	0
<i><b>Ischaemic coronary artery disorders</b></i>		
Acute myocardial infarction	1	0
Angina pectoris	1	0
Myocardial infarction	2	1
<i><b>Myocardial disorders NEC</b></i>		
Cardiomegaly	1	0
<i><b>Noninfectious myocarditis</b></i>		
Myocarditis	1	0
Myopericarditis	2	0
<i><b>Noninfectious pericarditis</b></i>		
Pericarditis	4	0
<i><b>Pericardial disorders NEC</b></i>		
Pericardial haemorrhage	1	1
<i><b>Rate and rhythm disorders NEC</b></i>		
Arrhythmia	2	0
Cardiac flutter	1	0
Extrasystoles	1	0
Postural orthostatic tachycardia syndrome	3	0
Tachycardia	15	0
<i><b>Supraventricular arrhythmias</b></i>		
Atrial fibrillation	7	0
Sinus tachycardia	1	0
Supraventricular tachycardia	2	0
<i><b>Ventricular arrhythmias and cardiac arrest</b></i>		
Cardio-respiratory arrest	1	1
Ventricular extrasystoles	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>95</b>	<b>5</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear discomfort	1	0
Ear pain	13	0
<i>Hearing losses</i>		
Deafness neurosensory	1	0
Deafness unilateral	1	0
<i>Hyperacusia</i>		
Hyperacusis	2	0
<i>Inner ear disorders NEC</i>		
Meniere's disease	1	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	1	0
Tinnitus	24	0
Vertigo	22	0
Vertigo labyrinthine	1	0
Vertigo positional	2	0
<b>Ear disorders SOC TOTAL</b>	<b>69</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<i>Thyroid hyperfunction disorders</i>		
Hyperthyroidism	1	0
<b>Endocrine disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i>Amblyopic vision impairment</i>		
Amblyopia	2	0
<i>Cataract conditions</i>		
Cataract	1	0
<i>Colour blindness (incl acquired)</i>		
Dyschromatopsia	1	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	1	0
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctival hyperaemia	1	0
<i>Corneal infections, oedemas and inflammations</i>		
Corneal oedema	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	2	0
Eyelid ptosis	2	0
Paralytic lagophthalmos	1	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Autoimmune uveitis	1	0
<i>Lacrimation disorders</i>		
Lacrimation increased	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Eyelid rash	1	0
Swelling of eyelid	4	0
<i>Ocular disorders NEC</i>		
Eye disorder	1	0
Eye pain	9	0
Eye swelling	5	0
Eyelid disorder	1	0
Eyelid pain	1	0
Periorbital swelling	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye irritation	2	0
Eye pruritus	3	0
Ocular hyperaemia	3	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	1	0
<i>Ocular sensation disorders</i>		
Photophobia	5	0
<i>Pupil disorders</i>		
Mydriasis	1	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Retinal vein occlusion	2	0
<i>Retinal structural change, deposit and degeneration</i>		
Chorioretinal disorder	1	0
Retinal tear	1	0
Retinal toxicity	1	0
<i>Retinal, choroid and vitreous infections and inflammations</i>		
Retinal vasculitis	1	0
<i>Scleral infections, irritations and inflammations</i>		
Episcleritis	1	0
<i>Visual disorders NEC</i>		
Charles Bonnet syndrome	1	0

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Reaction Name	Total	Fatal
<b>Eye disorders</b> Eye disorders cont'd		
Diplopia	2	0
Halo vision	1	0
Metamorphopsia	1	0
Photopsia	3	0
Vision blurred	15	0
<b>Visual field disorders</b>		
Visual field defect	2	0
<b>Visual impairment and blindness (excl colour blindness)</b>		
Blindness	3	0
Visual impairment	7	0
<b>Eye disorders SOC TOTAL</b>	<b>94</b>	<b>0</b>



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<b>Gastrointestinal disorders</b>		
<i>Acute and chronic pancreatitis</i>		
Pancreatitis	1	0
<i>Anal and rectal signs and symptoms</i>		
Anal hypoaesthesia	1	0
<i>Colitis (excl infective)</i>		
Colitis ulcerative	1	0
Crohn's disease	1	0
<i>Dental disorders NEC</i>		
Tooth erosion	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	60	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	7	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	5	0
Flatulence	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	22	0
Abdominal pain lower	1	0
Abdominal pain upper	26	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	7	0
Gastrooesophageal reflux disease	2	0
<i>Gastrointestinal disorders NEC</i>		
Gastrointestinal disorder	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	5	0
Breath odour	1	0
Dysphagia	2	0
Odynophagia	1	0
<i>Gastrointestinal vascular malformations</i>		
Gastric antral vascular ectasia	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival pain	2	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	1	0
<i>Intestinal haemorrhages</i>		
Rectal haemorrhage	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	199	0
Retching	4	0
Vomiting	61	0
Vomiting projectile	1	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematochezia	1	0
Melaena	1	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	5	0
Salivary hypersecretion	3	0
<i>Oral soft tissue disorders NEC</i>		

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Enlarged uvula	1	0
Oral lichen planus	1	0
Oral papule	1	0
<b>Oral soft tissue haemorrhages</b>		
Mouth haemorrhage	1	0
Oral blood blister	1	0
<b>Oral soft tissue signs and symptoms</b>		
Hypoaesthesia oral	4	0
Oral discomfort	1	0
Oral pain	4	0
Paraesthesia oral	22	0
<b>Oral soft tissue swelling and oedema</b>		
Lip swelling	15	0
Mouth swelling	4	0
<b>Pancreatic disorders NEC</b>		
Pancreatic disorder	1	0
<b>Salivary gland disorders NEC</b>		
Salivary gland pain	1	0
<b>Salivary gland enlargements</b>		
Submaxillary gland enlargement	1	0
<b>Stomatitis and ulceration</b>		
Aphthous ulcer	1	0
Mouth ulceration	9	0
Stomatitis	1	0
<b>Tongue disorders</b>		
Tongue disorder	1	0
<b>Tongue signs and symptoms</b>		
Glossodynia	1	0
Swollen tongue	12	0
Tongue eruption	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>511</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i>Administration site reactions NEC</i>		
Administration site warmth	1	0
Puncture site bruise	1	0
Vessel puncture site bruise	1	0
<i>Asthenic conditions</i>		
Asthenia	27	0
Chronic fatigue syndrome	1	0
Fatigue	329	0
Malaise	83	0
<i>Body temperature altered</i>		
Hypothermia	1	0
<i>Death and sudden death</i>		
Clinical death	1	1
Death	6	6
<i>Febrile disorders</i>		
Hyperpyrexia	1	0
Pyrexia	232	0
<i>Feelings and sensations NEC</i>		
Chills	155	0
Feeling abnormal	13	0
Feeling cold	11	0
Feeling hot	18	0
Feeling of body temperature change	5	0
Sensation of foreign body	1	0
Thirst	6	0
<i>Gait disturbances</i>		
Gait disturbance	2	0
Gait inability	4	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	2	0
Disease recurrence	1	0
Illness	22	0
Influenza like illness	49	0
Local reaction	4	0
Peripheral swelling	56	0
Secretion discharge	1	0
Swelling	36	0
Swelling face	13	0
<i>Inflammations</i>		
Inflammation	3	0
<i>Injection site reactions</i>		
Injected limb mobility decreased	1	0
Injection site bruising	3	0
Injection site discomfort	1	0
Injection site erythema	10	0
Injection site inflammation	1	0
Injection site mass	12	0
Injection site pain	44	0
Injection site pruritus	6	0
Injection site rash	1	0
Injection site reaction	1	0
Injection site scab	1	0

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Injection site swelling	10	0
<b>Mass conditions NEC</b>		
Mass	2	0
<b>Oedema NEC</b>		
Oedema	1	0
Oedema peripheral	3	0
<b>Pain and discomfort NEC</b>		
Axillary pain	20	0
Chest discomfort	22	0
Chest pain	37	0
Discomfort	6	0
Facial pain	4	0
Non-cardiac chest pain	1	0
Pain	87	0
Tenderness	13	0
<b>Therapeutic and nontherapeutic responses</b>		
Drug ineffective	8	0
Vaccination failure	1	0
<b>Ulcers NEC</b>		
Ulcer	1	0
<b>Vaccination site reactions</b>		
Vaccination site bruising	1	0
Vaccination site discomfort	1	0
Vaccination site erythema	13	0
Vaccination site induration	2	0
Vaccination site inflammation	1	0
Vaccination site mass	3	0
Vaccination site movement impairment	2	0
Vaccination site oedema	1	0
Vaccination site pain	37	0
Vaccination site pruritus	2	0
Vaccination site rash	1	0
Vaccination site reaction	1	0
Vaccination site swelling	14	0
Vaccination site urticaria	1	0
Vaccination site vesicles	1	0
Vaccination site warmth	6	0
<b>General disorders SOC TOTAL</b>	<b>1470</b>	<b>7</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	1	0
<i>Allergic conditions NEC</i>		
Hypersensitivity	6	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to chemicals	1	0
Allergy to vaccine	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	12	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	1	0
<i>Transplant rejections</i>		
Solid organ transplant rejection	1	0
Transplant rejection	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>24</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<i><b>Abdominal and gastrointestinal infections</b></i>		
Appendicitis	2	0
<i><b>Bacterial infections NEC</b></i>		
Cellulitis	8	0
<i><b>Breast infections</b></i>		
Breast abscess	1	0
<i><b>Candida infections</b></i>		
Candida infection	1	0
Oral candidiasis	4	0
<i><b>Coronavirus infections</b></i>		
COVID-19	28	1
COVID-19 pneumonia	1	1
Suspected COVID-19	2	0
<i><b>Ear infections</b></i>		
Ear infection	2	0
Labyrinthitis	2	0
<i><b>Eye and eyelid infections</b></i>		
Conjunctivitis	1	0
<i><b>Herpes viral infections</b></i>		
Genital herpes	1	0
Herpes simplex	1	0
Herpes zoster	18	0
Oral herpes	4	0
Varicella	1	0
<i><b>Infections NEC</b></i>		
Abscess	1	0
Infection	2	0
Injection site infection	1	0
Respiratory tract infection	1	0
Vaccine breakthrough infection	2	0
<i><b>Influenza viral infections</b></i>		
Influenza	19	0
<i><b>Lower respiratory tract and lung infections</b></i>		
Lower respiratory tract infection	1	0
Pneumonia	4	0
<i><b>Muscle and soft tissue infections</b></i>		
Soft tissue infection	1	0
<i><b>Sepsis, bacteraemia, viraemia and fungaemia NEC</b></i>		
Sepsis	1	0
<i><b>Upper respiratory tract infections</b></i>		
Nasopharyngitis	7	0
Sinusitis	3	0
Tonsillitis	1	0
Tracheitis	1	0
<i><b>Urinary tract infections</b></i>		
Kidney infection	2	0
Urinary tract infection	3	0
<i><b>Viral infections NEC</b></i>		
Pneumonia viral	1	0
Sweating fever	2	0
Viral tonsillitis	1	0
<b>Infections SOC TOTAL</b>	<b>131</b>	<b>2</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i>Accidental exposures to product</i>		
Accidental exposure to product	1	0
<i>Cardiovascular injuries</i>		
Vascular injury	1	0
<i>Cerebral injuries NEC</i>		
Subdural haemorrhage	1	0
<i>Conditions caused by cold</i>		
Chillblains	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure via breast milk	1	0
Maternal exposure during pregnancy	3	0
<i>Fractures and dislocations NEC</i>		
Multiple fractures	1	0
<i>Heat injuries (excl thermal burns)</i>		
Heat oedema	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	2	0
Vaccination error	1	0
<i>Muscle, tendon and ligament injuries</i>		
Muscle strain	1	0
<i>Non-site specific injuries NEC</i>		
Fall	4	0
Wound complication	1	0
<i>Occupational exposures</i>		
Occupational exposure to product	1	0
<i>Product administration errors and issues</i>		
Inappropriate schedule of product administration	2	0
Incorrect dose administered	1	0
Poor quality product administered	1	0
Product administered to patient of inappropriate age	1	0
<i>Site specific injuries NEC</i>		
Limb injury	4	0
<i>Skin injuries NEC</i>		
Contusion	9	0
<i>Vaccination related complications</i>		
Immunisation reaction	1	0
<b>Injuries SOC TOTAL</b>	<b>39</b>	<b>0</b>

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<b>Investigations</b>		
<i><b>Blood gas and acid base analyses</b></i>		
Blood lactic acid increased	1	0
Oxygen saturation decreased	1	0
<i><b>Carbohydrate tolerance analyses (incl diabetes)</b></i>		
Blood glucose decreased	1	0
Blood glucose increased	1	0
<i><b>Cell marker analyses</b></i>		
Prostatic specific antigen increased	1	0
<i><b>Chemistry analyses NEC</b></i>		
Inflammatory marker increased	1	0
<i><b>Coagulation and bleeding analyses</b></i>		
International normalised ratio decreased	2	0
International normalised ratio increased	6	0
<i><b>Heart rate and pulse investigations</b></i>		
Heart rate	1	0
Heart rate abnormal	1	0
Heart rate decreased	1	0
Heart rate increased	18	0
Heart rate irregular	2	0
Pulse abnormal	2	0
<i><b>Hepatobiliary function diagnostic procedures</b></i>		
Hepatic enzyme increased	1	0
<i><b>Imaging procedures NEC</b></i>		
Magnetic resonance imaging	1	0
X-ray	1	0
<i><b>Investigations NEC</b></i>		
Blood test	2	0
<i><b>Mineral and electrolyte analyses</b></i>		
Serum ferritin abnormal	1	0
<i><b>Neurologic diagnostic procedures</b></i>		
Nerve conduction studies	1	0
<i><b>Physical examination procedures and organ system status</b></i>		
Body temperature	3	0
Body temperature abnormal	1	0
Body temperature increased	13	0
Weight decreased	2	0
Weight increased	1	0
<i><b>Pituitary analyses anterior</b></i>		
Blood growth hormone	1	0
<i><b>Platelet analyses</b></i>		
Platelet count decreased	1	0
<i><b>Protein analyses NEC</b></i>		
C-reactive protein increased	1	0
<i><b>Red blood cell analyses</b></i>		
Haemoglobin decreased	1	0
<i><b>Respiratory and pulmonary function diagnostic procedures</b></i>		
Total lung capacity decreased	1	0
<i><b>Respiratory tract and thoracic imaging procedures</b></i>		
Chest X-ray	1	0
<i><b>Thyroid analyses</b></i>		
Tri-iodothyronine	1	0
<i><b>Urinalysis NEC</b></i>		



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Reaction Name	Total	Fatal
<b>Investigations</b>		
Investigations cont'd		
Blood urine present	1	0
<b><i>Vascular tests NEC (incl blood pressure)</i></b>		
Blood pressure increased	9	0
<b><i>Virus identification and serology</i></b>		
SARS-CoV-2 test positive	2	0
Viral test	1	0
<b><i>White blood cell analyses</i></b>		
Neutrophil count decreased	1	0
White blood cell count increased	1	0
<b>Investigations SOC TOTAL</b>	<b>88</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 24/197 All Yellow Card reports for COVID-19 Pfizer-BioNTech vaccine (Batch EL0141)

Report Run Date: 15-Mar-2024  
Earliest Reaction Date: 07-Jan-2020

Data Lock Date: 13-Mar-2024 18:30:03  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Decreased appetite	29	0
Hypophagia	1	0
<i><b>Calcium metabolism disorders</b></i>		
Hypocalcaemia	1	0
Tetany	1	0
<i><b>Diabetes mellitus (incl subtypes)</b></i>		
Diabetes mellitus	1	0
Type 1 diabetes mellitus	1	0
<i><b>Disorders of purine metabolism</b></i>		
Gout	1	0
<i><b>General nutritional disorders NEC</b></i>		
Feeding disorder	1	0
Food aversion	2	0
<i><b>Hypoglycaemic conditions NEC</b></i>		
Hypoglycaemia	3	0
<i><b>Potassium imbalance</b></i>		
Hyperkalaemia	1	0
<i><b>Total fluid volume decreased</b></i>		
Dehydration	1	0
<i><b>Total fluid volume increased</b></i>		
Fluid retention	2	0
<b>Metabolic disorders SOC TOTAL</b>	<b>45</b>	<b>0</b>

## Case Series Drug Analysis Print

**Name: FOI 24/197 All Yellow Card reports for COVID-19 Pfizer-BioNTech vaccine (Batch EL0141)**

Report Run Date: 15-Mar-2024  
Earliest Reaction Date: 07-Jan-2020

Data Lock Date: 13-Mar-2024 18:30:03  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Arthropathies NEC</i>		
Arthritis	5	0
<i>Bone disorders NEC</i>		
Osteitis	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	5	0
Pain in jaw	2	0
Spinal pain	1	0
<i>Bursal disorders</i>		
Bursitis	1	0
<i>Cartilage disorders</i>		
Costochondritis	1	0
Polychondritis	1	0
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	2	0
Reynold's syndrome	1	0
<i>Extremity deformities</i>		
Hand deformity	1	0
<i>Joint related disorders NEC</i>		
Periarthritis	3	0
<i>Joint related signs and symptoms</i>		
Arthralgia	144	0
Joint effusion	1	0
Joint stiffness	3	0
Joint swelling	9	0
<i>Muscle pains</i>		
Fibromyalgia	1	0
Myalgia	172	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle fatigue	3	0
Muscle spasms	8	0
Muscle twitching	7	0
<i>Muscle tone abnormalities</i>		
Nuchal rigidity	1	0
Torticollis	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	11	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Mobility decreased	5	0
Musculoskeletal stiffness	15	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	30	0
Flank pain	1	0
Limb discomfort	18	0
Musculoskeletal chest pain	1	0
Musculoskeletal discomfort	1	0
Musculoskeletal pain	2	0
Neck pain	28	0
Pain in extremity	129	0
<i>Osteoarthropathies</i>		
Osteoarthritis	1	0
<i>Rheumatoid arthropathies</i>		

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
Muscle & tissue disorders cont'd		
Rheumatoid arthritis	2	0
<b>Soft tissue disorders NEC</b>		
Axillary mass	5	0
Groin pain	1	0
<b>Spondyloarthropathies</b>		
Ankylosing spondylitis	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>625</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i><b>B-cell lymphomas NEC</b></i>		
B-cell lymphoma	1	1
<i><b>Breast and nipple neoplasms malignant</b></i>		
Breast cancer	1	0
Triple negative breast cancer	1	0
<i><b>Follicular lymphomas</b></i>		
Follicular lymphoma	1	0
Primary gastrointestinal follicular lymphoma	1	0
<i><b>Metastases to specified sites</b></i>		
Metastases to bone	1	0
Metastases to central nervous system	1	0
Metastases to spine	1	0
<i><b>Neoplasms malignant site unspecified NEC</b></i>		
Squamous cell carcinoma	1	0
<i><b>Renal neoplasms malignant</b></i>		
Renal cell carcinoma	1	0
<i><b>Skin neoplasms benign</b></i>		
Skin papilloma	1	0
<b>Neoplasms SOC TOTAL</b>	<b>11</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	1	0
<i>Autonomic nervous system disorders</i>		
Autonomic nervous system imbalance	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Brain stem stroke	1	0
Cerebral haemorrhage	1	1
Cerebrovascular accident	11	1
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	2	0
<i>Cervical spinal cord and nerve root disorders</i>		
Cervical radiculopathy	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	9	0
Coordination abnormal	1	0
Dysstasia	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	2	0
<i>Demyelinating disorders NEC</i>		
Acute disseminated encephalomyelitis	1	0
Demyelination	1	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	1	0
Depressed level of consciousness	1	0
Lethargy	48	0
Loss of consciousness	5	0
Somnolence	13	0
Syncope	16	0
<i>Dyskinesias and movement disorders NEC</i>		
Bradykinesia	1	0
Hypokinesia	1	0
Movement disorder	1	0
<i>Dystonias</i>		
Dystonia	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	8	0
Facial paralysis	7	0
Facial spasm	3	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	1	0
<i>Headaches NEC</i>		
Cluster headache	6	0
Headache	386	0
Occipital neuralgia	1	0
Sinus headache	4	0
Tension headache	5	0
Vascular headache	1	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Sciatica	1	0
<i>Memory loss (excl dementia)</i>		
Amnesia	5	0
Memory impairment	4	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
<b><i>Mental impairment (excl dementia and memory loss)</i></b>		
Cognitive disorder	2	0
Disturbance in attention	1	0
Mental impairment	1	0
<b><i>Migraine headaches</i></b>		
Migraine	35	0
Migraine with aura	3	0
Vestibular migraine	1	0
<b><i>Multiple sclerosis acute and progressive</i></b>		
Tumefactive multiple sclerosis	1	1
<b><i>Narcolepsy and hypersomnia</i></b>		
Hypersomnia	1	0
<b><i>Neurological signs and symptoms NEC</i></b>		
Brain fog	2	0
Clonus	1	0
Dizziness	128	0
Dizziness postural	17	0
Head discomfort	3	0
Inability to crawl	1	0
Neurological symptom	1	0
Persistent postural-perceptual dizziness	1	0
Presyncope	6	0
Unresponsive to stimuli	1	0
<b><i>Olfactory nerve disorders</i></b>		
Anosmia	4	0
Parosmia	6	0
<b><i>Paraesthesias and dysaesthesias</i></b>		
Burning sensation	11	0
Formication	2	0
Hemihypoaesthesia	1	0
Hemiparaesthesia	1	0
Hypoaesthesia	36	0
Paraesthesia	50	0
<b><i>Paralysis and paresis (excl cranial nerve)</i></b>		
Hemiplegia	1	0
Monoparesis	2	0
<b><i>Parkinson's disease and parkinsonism</i></b>		
Freezing phenomenon	1	0
<b><i>Partial complex seizures</i></b>		
Temporal lobe epilepsy	1	0
<b><i>Peripheral neuropathies NEC</i></b>		
Neuritis	1	0
Neuropathy peripheral	1	0
Peripheral sensory neuropathy	1	0
<b><i>Seizures and seizure disorders NEC</i></b>		
Epilepsy	1	0
Febrile convulsion	1	0
Partial seizures	1	0
Seizure	6	0
Seizure like phenomena	1	0
Tonic convulsion	1	0
<b><i>Sensory abnormalities NEC</i></b>		

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Ageusia	12	0
Allodynia	2	0
Aura	1	0
Dysgeusia	15	0
Neuralgia	5	0
Post herpetic neuralgia	2	0
Restless legs syndrome	3	0
Sensory disturbance	2	0
Taste disorder	10	0
<b><i>Speech and language abnormalities</i></b>		
Dysarthria	5	0
Repetitive speech	1	0
<b><i>Spinal cord and nerve root disorders NEC</i></b>		
Radiculopathy	1	0
<b><i>Transient cerebrovascular events</i></b>		
Transient ischaemic attack	3	0
<b><i>Tremor (excl congenital)</i></b>		
Tremor	27	0
<b>Nervous system disorders SOC TOTAL</b>	<b>978</b>	<b>3</b>



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Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i>Abortions spontaneous</i>		
Abortion spontaneous	3	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>3</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b><i>Device malfunction events NEC</i></b>		
Oversensing	1	0
<b><i>Product packaging issues</i></b>		
Product closure issue	1	0
<b><i>Product physical issues</i></b>		
Liquid product physical issue	1	0
<b><i>Product supply and availability issues</i></b>		
Product availability issue	1	0
<b>null SOC TOTAL</b>	<b>4</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<i>Abnormal behaviour NEC</i>		
Staring	1	0
<i>Anxiety symptoms</i>		
Agitation	3	0
Anxiety	13	0
Nervousness	3	0
Stress	3	0
<i>Behaviour and socialisation disturbances</i>		
Aversion	1	0
Social avoidant behaviour	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Mental fatigue	2	0
<i>Confusion and disorientation</i>		
Confusional state	15	0
Disorientation	2	0
<i>Deliria</i>		
Delirium	1	0
<i>Depressive disorders</i>		
Depression	1	0
<i>Dissociative states</i>		
Dissociative amnesia	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	1	0
Insomnia	19	0
<i>Dyssomnias</i>		
Poor quality sleep	4	0
<i>Emotional and mood disturbances NEC</i>		
Anger	2	0
Emotional disorder	1	0
Irritability	3	0
Mood altered	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	2	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	6	0
Hallucination, auditory	1	0
Hallucination, visual	1	0
<i>Increased physical activity levels</i>		
Restlessness	3	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	6	0
<i>Panic attacks and disorders</i>		
Panic attack	2	0
Panic disorder	1	0
<i>Parasomnias</i>		
Abnormal dreams	2	0
Nightmare	5	0
<i>Sleep disorders NEC</i>		
Sleep disorder	5	0
<i>Stereotypies and automatisms</i>		
Stereotypy	1	0
<i>Thinking disturbances</i>		

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> Psychiatric disorders cont'd		
Bradyphrenia	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>114</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i><b>Bladder and urethral symptoms</b></i>		
Dysuria	1	0
Urinary incontinence	1	0
Urinary retention	1	0
<i><b>Glomerulonephritis and nephrotic syndrome</b></i>		
Glomerulonephritis minimal lesion	1	0
<i><b>Renal failure and impairment</b></i>		
Acute kidney injury	1	1
Renal impairment	2	0
<i><b>Structural and obstructive urethral disorders (excl congenital)</b></i>		
Urethral stenosis	1	0
<i><b>Ureteric disorders NEC</b></i>		
Ureteric stenosis	1	0
<i><b>Urinary abnormalities</b></i>		
Chromaturia	2	0
<i><b>Urinary tract signs and symptoms NEC</b></i>		
Haemorrhage urinary tract	1	0
Renal pain	4	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>16</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Breast disorders NEC</b></i>		
Breast mass	3	0
<i><b>Breast signs and symptoms</b></i>		
Breast discharge	1	0
Breast pain	7	0
Breast swelling	4	0
Breast tenderness	1	0
<i><b>Erection and ejaculation conditions and disorders</b></i>		
Erectile dysfunction	2	0
<i><b>Menopausal effects on the genitourinary tract</b></i>		
Postmenopausal haemorrhage	3	0
<i><b>Menstruation and uterine bleeding NEC</b></i>		
Dysmenorrhoea	6	0
Intermenstrual bleeding	2	0
Menstrual disorder	13	0
Menstruation irregular	10	0
Premenstrual syndrome	1	0
<i><b>Menstruation with decreased bleeding</b></i>		
Amenorrhoea	8	0
Hypomenorrhoea	5	0
Menstruation delayed	6	0
Oligomenorrhoea	1	0
<i><b>Menstruation with increased bleeding</b></i>		
Heavy menstrual bleeding	15	0
Polymenorrhoea	4	0
<i><b>Ovarian and fallopian tube cysts and neoplasms</b></i>		
Ovarian cyst	1	0
Polycystic ovaries	1	0
<i><b>Pelvis and broad ligament disorders NEC</b></i>		
Adnexa uteri pain	1	0
<i><b>Reproductive tract signs and symptoms NEC</b></i>		
Pelvic pain	1	0
<i><b>Scrotal disorders NEC</b></i>		
Scrotal pain	1	0
<i><b>Uterine disorders NEC</b></i>		
Endometriosis	1	0
<i><b>Vulvovaginal disorders NEC</b></i>		
Vaginal haemorrhage	10	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>108</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Dyspnoea	66	0
Dyspnoea exertional	1	0
Hyperventilation	1	0
Hypopnoea	2	0
Respiration abnormal	2	0
Tachypnoea	1	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	6	0
Obstructive airways disorder	1	0
Wheezing	6	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	31	0
Productive cough	1	0
<i><b>Lower respiratory tract signs and symptoms</b></i>		
Pulmonary pain	2	0
Rales	1	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	1	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	12	0
<i><b>Paranasal sinus disorders (excl infections and neoplasms)</b></i>		
Sinus congestion	2	0
<i><b>Parenchymal lung disorders NEC</b></i>		
Pulmonary fibrosis	1	0
<i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>		
Pharyngeal haemorrhage	1	0
Pharyngeal swelling	6	0
Tonsillar hypertrophy	3	0
Tonsillar inflammation	1	0
<i><b>Pleural infections and inflammations</b></i>		
Pleurisy	1	0
<i><b>Pulmonary oedemas</b></i>		
Pulmonary congestion	1	0
Pulmonary oedema	2	0
<i><b>Pulmonary thrombotic and embolic conditions</b></i>		
Pulmonary embolism	11	1
Pulmonary thrombosis	1	1
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Aphonia	1	0
Catarrh	1	0
Dry throat	4	0
Dysphonia	3	0
Increased viscosity of upper respiratory secretion	1	0
Oropharyngeal discomfort	2	0
Oropharyngeal pain	38	0
Rhinorrhoea	5	0
Sinus pain	3	0
Sneezing	2	0
Throat irritation	4	0
Throat tightness	3	0
<b>Respiratory disorders SOC TOTAL</b>	<b>231</b>	<b>2</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<i>Acnes</i>		
Acne	1	0
<i>Alopecias</i>		
Alopecia	3	0
Alopecia areata	1	0
<i>Angioedemas</i>		
Angioedema	3	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	3	0
Hyperhidrosis	22	0
Miliaria	1	0
Night sweats	12	0
<i>Bullous conditions</i>		
Blister	7	0
Blood blister	1	0
Pemphigoid	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	2	0
Pain of skin	7	0
Papule	2	0
Sensitive skin	2	0
Skin burning sensation	4	0
Skin discolouration	3	0
Skin lesion	1	0
Skin reaction	1	0
Skin swelling	4	0
Skin tightness	1	0
Skin warm	5	0
<i>Dermatitis and eczema</i>		
Dermatitis	2	0
Dermatitis allergic	4	0
Dermatitis contact	1	0
Eczema	6	0
<i>Erythemas</i>		
Erythema	45	0
<i>Exfoliative conditions</i>		
Skin exfoliation	1	0
<i>Hyperkeratoses</i>		
Hyperkeratosis	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Splinter haemorrhages	1	0
<i>Papulosquamous conditions</i>		
Pityriasis rosea	3	0
<i>Photosensitivity and photodermatitis conditions</i>		
Photosensitivity reaction	1	0
<i>Pigmentation changes NEC</i>		
Pigmentation disorder	1	0
<i>Pilar disorders NEC</i>		
Pseudofolliculitis	1	0
<i>Pruritus NEC</i>		
Pruritus	79	0
<i>Psoriatic conditions</i>		



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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Psoriasis	2	0
<b>Purpura and related conditions</b>		
Henoch-Schonlein purpura	1	0
Petechiae	1	0
Purpura	5	0
<b>Rashes, eruptions and exanthems NEC</b>		
Rash	100	0
Rash erythematous	17	0
Rash macular	4	0
Rash maculo-papular	1	0
Rash morbilliform	1	0
Rash papular	10	0
Rash pruritic	17	0
Rash vesicular	1	0
<b>Skin and subcutaneous conditions NEC</b>		
Cellulite	1	0
<b>Skin haemorrhages</b>		
Haemorrhage subcutaneous	1	0
<b>Skin vasculitides</b>		
Cutaneous vasculitis	2	0
Vasculitic rash	2	0
<b>Urticarias</b>		
Urticaria	22	0
Urticaria thermal	1	0
<b>Skin disorders SOC TOTAL</b>	<b>422</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i>Disability issues</i>		
Bedridden	1	0
Physical disability	1	0
<b>Social circumstances SOC TOTAL</b>	<b>2</b>	<b>0</b>

## Case Series Drug Analysis Print

Name: FOI 24/197 All Yellow Card reports for COVID-19 Pfizer-BioNTech vaccine (Batch EL0141)

Report Run Date: 15-Mar-2024

Data Lock Date: 13-Mar-2024 18:30:03

Earliest Reaction Date: 07-Jan-2020

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Immunisations</i>		
COVID-19 immunisation	2	0
Immunisation	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>3</b>	<b>0</b>

## Case Series Drug Analysis Print

**Name: FOI 24/197 All Yellow Card reports for COVID-19 Pfizer-BioNTech vaccine (Batch EL0141)**

Report Run Date: 15-Mar-2024  
Earliest Reaction Date: 07-Jan-2020

Data Lock Date: 13-Mar-2024 18:30:03  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i><b>Aortic aneurysms and dissections</b></i>		
Aortic dissection	1	0
<i><b>Aortic embolism and thrombosis</b></i>		
Aortic embolus	1	0
<i><b>Arterial infections and inflammations</b></i>		
Arteritis	1	0
<i><b>Blood pressure disorders NEC</b></i>		
Blood pressure fluctuation	1	0
<i><b>Circulatory collapse and shock</b></i>		
Circulatory collapse	2	0
Neurogenic shock	2	0
<i><b>Haemorrhages NEC</b></i>		
Haematoma	1	0
Haemorrhage	6	0
<i><b>Lymphoedemas</b></i>		
Lymphoedema	4	0
<i><b>Non-site specific embolism and thrombosis</b></i>		
Embolism	2	0
Thrombosis	7	0
Venous thrombosis	1	0
<i><b>Non-site specific necrosis and vascular insufficiency NEC</b></i>		
Infarction	1	0
Vasospasm	1	0
<i><b>Non-site specific vascular disorders NEC</b></i>		
Vein discolouration	1	0
Vein rupture	1	0
<i><b>Peripheral embolism and thrombosis</b></i>		
Blue toe syndrome	1	0
Deep vein thrombosis	5	0
<i><b>Peripheral vascular disorders NEC</b></i>		
Cyanosis	1	0
Flushing	6	0
Hot flush	15	0
<i><b>Peripheral vasoconstriction, necrosis and vascular insufficiency</b></i>		
Claudication of jaw muscles	1	0
Peripheral coldness	3	0
<i><b>Phlebitis NEC</b></i>		
Phlebitis	1	0
<i><b>Site specific vascular disorders NEC</b></i>		
Pallor	7	0
<i><b>Vascular hypertensive disorders NEC</b></i>		
Diastolic hypertension	1	0
Essential hypertension	1	0
Hypertension	10	0
<i><b>Vascular hypotensive disorders</b></i>		
Hypotension	9	0
Orthostatic hypotension	3	0
<i><b>Vasculitides NEC</b></i>		
Vasculitis	2	0
<b>Vascular disorders SOC TOTAL</b>	<b>99</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>5361</b>	<b>21</b>

## Case Series Drug Analysis Print

Name: FOI 24/197 All Yellow Card reports for COVID-19 Pfizer-BioNTech vaccine (Batch EL0141)

Report Run Date: 15-Mar-2024

Data Lock Date: 13-Mar-2024 18:30:03

Earliest Reaction Date: 07-Jan-2020

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
TOTAL REPORTS	1841	
TOTAL FATAL OUTCOME REPORTS		21