

## Case Series Drug Analysis Print

### Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023

Data Lock Date: 24-Feb-2023 18:30:04

Earliest Reaction Date: 14-Nov-2005

MedDRA Version: MedDRA 25.1

FOI 23/124 - All UK spontaneous reports for Pandemrix vaccine up  
Pandemrix Vaccine to and including DLP 24/02/2023  
Analysis Print:

## Case Series Drug Analysis Print

### Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023  
 Earliest Reaction Date: 14-Nov-2005

Data Lock Date: 24-Feb-2023 18:30:04  
 MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<b><i>Anaemias NEC</i></b>		
Anaemia	3	0
<b><i>Anaemias haemolytic immune</i></b>		
Autoimmune haemolytic anaemia	1	0
<b><i>Haematological disorders</i></b>		
Methaemoglobinaemia	1	0
<b><i>Lymphatic system disorders NEC</i></b>		
Lymph node pain	3	0
Lymphadenitis	3	0
Lymphadenopathy	71	0
<b><i>Marrow depression and hypoplastic anaemias</i></b>		
Pancytopenia	1	1
<b><i>Spleen disorders</i></b>		
Splenomegaly	1	0
<b><i>Thrombocytopenias</i></b>		
Immune thrombocytopenia	11	0
Thrombocytopenia	4	0
<b>Blood disorders SOC TOTAL</b>	<b>99</b>	<b>1</b>

## Case Series Drug Analysis Print

### Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023

Data Lock Date: 24-Feb-2023 18:30:04

Earliest Reaction Date: 14-Nov-2005

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i><b>Cardiac disorders NEC</b></i>		
Cardiac disorder	1	0
Cardiovascular disorder	1	0
<i><b>Cardiac signs and symptoms NEC</b></i>		
Palpitations	29	0
<i><b>Ischaemic coronary artery disorders</b></i>		
Angina pectoris	1	0
Myocardial infarction	4	2
<i><b>Noninfectious pericarditis</b></i>		
Pericarditis	1	0
<i><b>Rate and rhythm disorders NEC</b></i>		
Bradycardia	1	0
Extrasystoles	1	0
Tachycardia	13	0
Tachycardia foetal	1	0
<i><b>Supraventricular arrhythmias</b></i>		
Atrial fibrillation	2	0
Sinus tachycardia	2	0
Supraventricular tachycardia	2	0
<b>Cardiac disorders SOC TOTAL</b>	<b>59</b>	<b>2</b>

## Case Series Drug Analysis Print

### Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023

Data Lock Date: 24-Feb-2023 18:30:04

Earliest Reaction Date: 14-Nov-2005

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Cardiovascular disorders congenital NEC</i>		
Congenital cardiovascular anomaly	1	0
<i>Diaphragmatic disorders congenital</i>		
Congenital diaphragmatic eventration	1	0
<i>Hearing disorders congenital</i>		
Deafness congenital	1	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Developmental hip dysplasia	1	0
<i>Non-site specific muscle disorders congenital</i>		
Muscular dystrophy	1	0
<i>Renal disorders congenital</i>		
Pelvic kidney	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>6</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023

Data Lock Date: 24-Feb-2023 18:30:04

Earliest Reaction Date: 14-Nov-2005

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear pain	12	0
<i>Hearing losses</i>		
Deafness	2	0
Deafness neurosensory	2	0
Hypoacusis	1	0
<i>Inner ear disorders NEC</i>		
Inner ear disorder	1	0
Meniere's disease	1	0
Vestibular disorder	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	13	0
Vertigo	11	0
Vertigo positional	2	0
<b>Ear disorders SOC TOTAL</b>	<b>46</b>	<b>0</b>

# Case Series Drug Analysis Print

## Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023

Data Lock Date: 24-Feb-2023 18:30:04

Earliest Reaction Date: 14-Nov-2005

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<i>Acute and chronic thyroiditis</i>		
Thyroiditis	1	0
<i>Thyroid disorders NEC</i>		
Thyroid disorder	1	0
<b>Endocrine disorders SOC TOTAL</b>	<b>2</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023

Data Lock Date: 24-Feb-2023 18:30:04

Earliest Reaction Date: 14-Nov-2005

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i><b>Eyelid movement disorders</b></i>		
Blepharospasm	2	0
Excessive eye blinking	1	0
Eyelid ptosis	2	0
<i><b>Glaucomas (excl congenital)</b></i>		
Ocular hypertension	1	0
<i><b>Lacrimation disorders</b></i>		
Dry eye	1	0
Lacrimation increased	3	0
<i><b>Lid, lash and lacrimal infections, irritations and inflammations</b></i>		
Blepharitis allergic	1	0
Eyelid oedema	3	0
Swelling of eyelid	2	0
<i><b>Ocular disorders NEC</b></i>		
Eye disorder	1	0
Eye pain	19	0
Eye swelling	8	0
Eyelid disorder	1	0
Eyelid pain	1	0
<i><b>Ocular infections, inflammations and associated manifestations</b></i>		
Eye discharge	2	0
Eye irritation	3	0
Eye pruritus	1	0
Ocular hyperaemia	1	0
<i><b>Ocular nerve and muscle disorders</b></i>		
Eye movement disorder	2	0
Ocular myasthenia	1	0
<i><b>Ocular sensation disorders</b></i>		
Abnormal sensation in eye	1	0
Asthenopia	2	0
Photophobia	6	0
<i><b>Optic disc abnormalities NEC</b></i>		
Papilloedema	1	0
<i><b>Pupil disorders</b></i>		
Mydriasis	1	0
<i><b>Retinal bleeding and vascular disorders (excl retinopathy)</b></i>		
Retinal haemorrhage	1	0
<i><b>Retinal, choroid and vitreous infections and inflammations</b></i>		
Retinal vasculitis	1	0
<i><b>Visual disorders NEC</b></i>		
Diplopia	1	0
Photopsia	1	0
Vision blurred	14	0
<i><b>Visual impairment and blindness (excl colour blindness)</b></i>		
Blindness	1	0
Visual acuity reduced	2	0
Visual acuity reduced transiently	1	0
Visual impairment	7	0
<b>Eye disorders SOC TOTAL</b>	<b>96</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023

Data Lock Date: 24-Feb-2023 18:30:04

Earliest Reaction Date: 14-Nov-2005

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Abdominal findings abnormal</i>		
Abdominal mass	1	0
<i>Acute and chronic pancreatitis</i>		
Pancreatitis	1	0
Pancreatitis acute	1	0
<i>Colitis (excl infective)</i>		
Crohn's disease	2	0
<i>Dental developmental disorders and anomalies</i>		
Tooth malformation	1	0
<i>Dental pain and sensation disorders</i>		
Toothache	4	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	153	0
Diarrhoea haemorrhagic	2	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	7	0
Epigastric discomfort	1	0
<i>Faecal abnormalities NEC</i>		
Mucous stools	1	0
<i>Flatulence, bloating and distension</i>		
Flatulence	2	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	46	0
Abdominal pain lower	4	0
Abdominal pain upper	62	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	3	0
Gastrooesophageal reflux disease	1	0
<i>Gastrointestinal disorders NEC</i>		
Gastrointestinal disorder	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Gastrointestinal motility disorder	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	11	0
Anal incontinence	1	0
Breath odour	1	0
Dysphagia	4	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Irritable bowel syndrome	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival pain	1	0
<i>Intestinal haemorrhages</i>		
Rectal haemorrhage	2	0
<i>Nausea and vomiting symptoms</i>		
Nausea	275	0
Regurgitation	1	0
Retching	1	0
Vomiting	218	0
Vomiting projectile	2	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	1	0
Haematemesis	2	0
Haematochezia	3	0

## Case Series Drug Analysis Print

### Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023

Data Lock Date: 24-Feb-2023 18:30:04

Earliest Reaction Date: 14-Nov-2005

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
<b><i>Oesophagitis (excl infective)</i></b>		
Oesophagitis	1	0
<b><i>Oral dryness and saliva altered</i></b>		
Dry mouth	12	0
Lip dry	1	0
<b><i>Oral soft tissue disorders NEC</i></b>		
Chapped lips	1	0
Lip blister	1	0
<b><i>Oral soft tissue signs and symptoms</i></b>		
Hypoaesthesia oral	6	0
Lip erythema	1	0
Oral discomfort	1	0
Oral mucosal blistering	1	0
Oral pain	2	0
Oral pruritus	1	0
Paraesthesia oral	20	0
<b><i>Oral soft tissue swelling and oedema</i></b>		
Lip swelling	16	0
Mouth swelling	1	0
<b><i>Stomatitis and ulceration</i></b>		
Mouth ulceration	2	0
Stomatitis	2	0
<b><i>Tongue disorders</i></b>		
Glossitis	1	0
Tongue disorder	1	0
Tongue ulceration	1	0
Trichoglossia	1	0
<b><i>Tongue signs and symptoms</i></b>		
Glossodynia	1	0
Protrusion tongue	1	0
Swollen tongue	6	0
Tongue coated	1	0
Tongue discolouration	1	0
Tongue erythema	1	0
Tongue oedema	2	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>904</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023

Data Lock Date: 24-Feb-2023 18:30:04

Earliest Reaction Date: 14-Nov-2005

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>General disorders</b>		
<b><i>Administration site reactions NEC</i></b>		
Administration site pain	1	0
Vessel puncture site swelling	1	0
<b><i>Application and instillation site reactions</i></b>		
Application site bruise	3	0
Application site erythema	1	0
Application site induration	1	0
Application site pain	26	0
Application site pruritus	5	0
Application site reaction	2	0
Application site swelling	1	0
Application site warmth	2	0
<b><i>Asthenic conditions</i></b>		
Asthenia	51	0
Chronic fatigue syndrome	1	0
Fatigue	255	0
Malaise	157	0
<b><i>Body temperature altered</i></b>		
Temperature regulation disorder	1	0
<b><i>Death and sudden death</i></b>		
Death	5	5
Death neonatal	2	2
Sudden death	4	4
<b><i>Febrile disorders</i></b>		
Pyrexia	399	0
<b><i>Feelings and sensations NEC</i></b>		
Chills	139	0
Feeling abnormal	23	0
Feeling cold	13	0
Feeling drunk	1	0
Feeling hot	35	0
Feeling jittery	1	0
Feeling of body temperature change	15	0
Hangover	2	0
Hunger	1	0
Thirst	3	0
<b><i>Gait disturbances</i></b>		
Gait disturbance	11	0
Gait inability	3	0
Loss of control of legs	1	0
<b><i>General signs and symptoms NEC</i></b>		
Condition aggravated	4	0
Crepitations	1	0
Crying	5	0
Foaming at mouth	1	0
Ill-defined disorder	3	0
Illness	19	0
Induration	2	0
Influenza like illness	224	0
Irritability postvaccinal	1	0
Local reaction	59	0
Moaning	1	0
Multiple organ dysfunction syndrome	2	1

## Case Series Drug Analysis Print

### Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023

Data Lock Date: 24-Feb-2023 18:30:04

Earliest Reaction Date: 14-Nov-2005

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Peripheral swelling	178	0
Swelling	88	0
Swelling face	19	0
<b>Inflammations</b>		
Inflammation	3	0
<b>Injection site reactions</b>		
Injected limb mobility decreased	1	0
Injection site bruising	12	0
Injection site cyst	2	0
Injection site discharge	1	0
Injection site discolouration	3	0
Injection site discomfort	2	0
Injection site erythema	46	0
Injection site haematoma	1	0
Injection site hypersensitivity	1	0
Injection site hypoaesthesia	1	0
Injection site induration	10	0
Injection site inflammation	88	0
Injection site irritation	1	0
Injection site mass	10	0
Injection site movement impairment	1	0
Injection site oedema	12	0
Injection site pain	143	0
Injection site paraesthesia	1	0
Injection site phlebitis	1	0
Injection site pruritus	14	0
Injection site rash	15	0
Injection site reaction	10	0
Injection site swelling	69	0
Injection site urticaria	3	0
Injection site vesicles	1	0
Injection site warmth	10	0
<b>Interactions</b>		
Drug interaction	2	0
<b>Mucosal findings abnormal</b>		
Mucosal haemorrhage	1	0
<b>Oedema NEC</b>		
Face oedema	1	0
Localised oedema	1	0
Oedema peripheral	1	0
<b>Pain and discomfort NEC</b>		
Axillary pain	5	0
Chest discomfort	41	0
Chest pain	27	0
Discomfort	4	0
Facial pain	3	0
Non-cardiac chest pain	3	0
Pain	136	0
Tenderness	15	0
<b>Therapeutic and nontherapeutic responses</b>		
Adverse drug reaction	1	0
Adverse event	1	0
Adverse reaction	1	0

# Case Series Drug Analysis Print

## Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023

Data Lock Date: 24-Feb-2023 18:30:04

Earliest Reaction Date: 14-Nov-2005

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Drug ineffective	1	0
<b>Vaccination site reactions</b>		
Extensive swelling of vaccinated limb	2	0
Vaccination site pain	13	0
Vaccination site rash	1	0
Vaccination site reaction	2	0
<b>General disorders SOC TOTAL</b>	<b>2497</b>	<b>12</b>

## Case Series Drug Analysis Print

### Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023

Data Lock Date: 24-Feb-2023 18:30:04

Earliest Reaction Date: 14-Nov-2005

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i>Cholestasis and jaundice</i>		
Jaundice	2	0
<i>Hepatic failure and associated disorders</i>		
Hepatic failure	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Non-alcoholic fatty liver	1	0
<b>Hepatic disorders SOC TOTAL</b>	<b>5</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023

Data Lock Date: 24-Feb-2023 18:30:04

Earliest Reaction Date: 14-Nov-2005

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i><b>Allergic conditions NEC</b></i>		
Hypersensitivity	16	0
Multiple allergies	1	0
Type I hypersensitivity	1	0
Type IV hypersensitivity reaction	1	0
<i><b>Allergies to foods, food additives, drugs and other chemicals</b></i>		
Allergy to chemicals	1	0
Allergy to vaccine	1	0
Food allergy	1	0
<i><b>Anaphylactic and anaphylactoid responses</b></i>		
Anaphylactic reaction	20	0
Anaphylactic shock	2	0
Anaphylactoid reaction	3	0
<i><b>Immune and associated conditions NEC</b></i>		
Immune system disorder	2	0
Immunisation reaction	7	0
<i><b>Immunodeficiency disorders NEC</b></i>		
Immunosuppression	1	0
<i><b>Transplant rejections</b></i>		
Intestine transplant rejection	1	0
Transplant rejection	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>59</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023

Data Lock Date: 24-Feb-2023 18:30:04

Earliest Reaction Date: 14-Nov-2005

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Infections</b>		
<b><i>Abdominal and gastrointestinal infections</i></b>		
Diarrhoea infectious	1	0
Gastroenteritis	1	1
<b><i>Bacterial infections NEC</i></b>		
Bacterial infection	1	0
Cellulitis	22	0
Conjunctivitis bacterial	1	0
Cronobacter infection	1	0
Intestinal gangrene	1	1
<b><i>Central nervous system and spinal infections</i></b>		
Encephalitis	1	0
<b><i>Cryptococcal infections</i></b>		
Gastroenteritis cryptococcal	1	0
<b><i>Dental and oral soft tissue infections</i></b>		
Parotitis	2	0
Tooth infection	1	0
<b><i>Ear infections</i></b>		
Ear infection	1	0
<b><i>Eye and eyelid infections</i></b>		
Conjunctivitis	4	0
Eye infection	1	0
<b><i>Herpes viral infections</i></b>		
Herpes zoster	5	0
Oral herpes	1	0
Varicella	2	0
<b><i>Infections NEC</i></b>		
Abscess	1	0
Infection	6	0
Injection site abscess	2	0
Injection site infection	2	0
Localised infection	2	0
Lymph gland infection	1	0
Respiratory tract infection	1	0
<b><i>Infectious transmissions</i></b>		
Suspected transmission of an infectious agent via product	1	0
<b><i>Influenza viral infections</i></b>		
Influenza	15	0
<b><i>Lower respiratory tract and lung infections</i></b>		
Bronchitis	2	0
Lower respiratory tract infection	17	0
Pneumonia	4	1
<b><i>Male reproductive tract infections</i></b>		
Orchitis	1	0
<b><i>Neisseria infections</i></b>		
Meningococcal sepsis	1	1
<b><i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i></b>		
Sepsis	2	0
<b><i>Skin structures and soft tissue infections</i></b>		
Skin infection	1	0
<b><i>Staphylococcal infections</i></b>		
Furuncle	1	0
<b><i>Upper respiratory tract infections</i></b>		
Croup infectious	1	0

## Case Series Drug Analysis Print

### Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023

Data Lock Date: 24-Feb-2023 18:30:04

Earliest Reaction Date: 14-Nov-2005

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
Laryngitis	1	0
Nasopharyngitis	27	0
Pharyngitis	1	0
Rhinitis	6	0
Sinusitis	1	0
Tonsillitis	1	0
Upper respiratory tract infection	2	0
<b>Urinary tract infections</b>		
Kidney infection	2	0
Urinary tract infection	2	0
<b>Viral infections NEC</b>		
Encephalitis viral	1	0
Pneumonia viral	1	0
Post viral fatigue syndrome	3	0
Sweating fever	3	0
Vestibular neuronitis	1	0
Viral infection	2	0
<b>Infections SOC TOTAL</b>	<b>162</b>	<b>4</b>

## Case Series Drug Analysis Print

### Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023

Data Lock Date: 24-Feb-2023 18:30:04

Earliest Reaction Date: 14-Nov-2005

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Injuries</b>		
<b><i>Abdominal and gastrointestinal injuries NEC</i></b>		
Tooth fracture	1	0
<b><i>Anaesthetic and allied procedural complications</i></b>		
Delayed recovery from anaesthesia	1	0
<b><i>Exposures associated with pregnancy, delivery and lactation</i></b>		
Exposure during pregnancy	9	0
Foetal exposure during pregnancy	4	0
Maternal exposure before pregnancy	1	0
Maternal exposure during pregnancy	1	0
Maternal exposure timing unspecified	3	0
<b><i>Eye injuries NEC</i></b>		
Retinal injury	1	0
<b><i>Fractures and dislocations NEC</i></b>		
Joint dislocation	1	0
<b><i>Gastrointestinal and hepatobiliary procedural complications</i></b>		
Procedural nausea	1	0
<b><i>Heat injuries (excl thermal burns)</i></b>		
Heat oedema	1	0
<b><i>Medication errors, product use errors and issues NEC</i></b>		
Medication error	1	0
<b><i>Muscle, tendon and ligament injuries</i></b>		
Ligament sprain	1	0
Muscle strain	1	0
<b><i>Nerve injuries NEC</i></b>		
Nerve injury	2	0
<b><i>Neurological and psychiatric procedural complications</i></b>		
Procedural dizziness	1	0
<b><i>Non-site specific injuries NEC</i></b>		
Fall	10	0
<b><i>Non-site specific procedural complications</i></b>		
Infusion related reaction	1	0
Post procedural complication	1	0
<b><i>Overdoses NEC</i></b>		
Intentional overdose	2	0
<b><i>Product administration errors and issues</i></b>		
Accidental overdose	2	0
Inappropriate schedule of product administration	1	0
Product administered to patient of inappropriate age	1	0
<b><i>Skin injuries NEC</i></b>		
Contusion	15	0
Skin laceration	2	0
<b><i>Transplantation complications</i></b>		
Complications of transplanted liver	1	0
Transplant dysfunction	1	0
<b><i>Vaccination related complications</i></b>		
Post vaccination syndrome	3	0
<b>Injuries SOC TOTAL</b>	<b>70</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023

Data Lock Date: 24-Feb-2023 18:30:04

Earliest Reaction Date: 14-Nov-2005

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Investigations</b>		
<i><b>Blood gas and acid base analyses</b></i>		
Oxygen saturation decreased	2	0
<i><b>Carbohydrate tolerance analyses (incl diabetes)</b></i>		
Blood glucose decreased	1	0
Blood glucose increased	4	0
<i><b>Cell marker analyses</b></i>		
HLA marker study positive	1	0
<i><b>Cerebrospinal fluid tests (excl microbiology)</b></i>		
CSF protein increased	1	0
<i><b>Coagulation and bleeding analyses</b></i>		
International normalised ratio increased	4	0
<i><b>Foetal and neonatal diagnostic procedures</b></i>		
Foetal heart rate abnormal	1	0
<i><b>Heart rate and pulse investigations</b></i>		
Heart rate increased	7	0
Heart rate irregular	2	0
<i><b>Hepatobiliary function diagnostic procedures</b></i>		
Transaminases increased	1	0
<i><b>Investigations NEC</b></i>		
Quality of life decreased	2	0
<i><b>Metabolism tests NEC</b></i>		
Urine ketone body present	1	0
<i><b>Mineral and electrolyte analyses</b></i>		
Blood iron decreased	1	0
<i><b>Neurologic diagnostic procedures</b></i>		
Sleep study abnormal	1	0
<i><b>Physical examination procedures and organ system status</b></i>		
Body temperature	1	0
Body temperature decreased	3	0
Body temperature fluctuation	2	0
Body temperature increased	112	0
Grip strength decreased	1	0
Respiratory rate decreased	1	0
Respiratory rate increased	1	0
Weight decreased	5	0
Weight increased	9	0
<i><b>Platelet analyses</b></i>		
Platelet count decreased	3	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>Renal function analyses</b></i>		
Blood creatinine increased	1	0
<i><b>Respiratory and pulmonary function diagnostic procedures</b></i>		
Forced expiratory volume increased	2	0
<i><b>Urinalysis NEC</b></i>		
Blood urine present	2	0
Protein urine present	1	0
<i><b>Vascular tests NEC (incl blood pressure)</b></i>		
Blood pressure abnormal	2	0
Blood pressure decreased	5	0
Blood pressure increased	3	0

# Case Series Drug Analysis Print

## Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023

Data Lock Date: 24-Feb-2023 18:30:04

Earliest Reaction Date: 14-Nov-2005

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
<i>White blood cell analyses</i>		
White blood cell count decreased	1	0
<b>Investigations SOC TOTAL</b>	<b>186</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023

Data Lock Date: 24-Feb-2023 18:30:04

Earliest Reaction Date: 14-Nov-2005

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Decreased appetite	38	0
Hypophagia	1	0
Increased appetite	2	0
<i><b>Diabetes mellitus (incl subtypes)</b></i>		
Diabetes mellitus inadequate control	1	0
Type 1 diabetes mellitus	2	0
<i><b>General nutritional disorders NEC</b></i>		
Feeding disorder	2	0
Food aversion	1	0
<i><b>Hyperglycaemic conditions NEC</b></i>		
Hyperglycaemia	1	0
<i><b>Hypoglycaemic conditions NEC</b></i>		
Hypoglycaemia	2	0
<i><b>Total fluid volume decreased</b></i>		
Dehydration	6	0
<b>Metabolic disorders SOC TOTAL</b>	<b>56</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023

Data Lock Date: 24-Feb-2023 18:30:04

Earliest Reaction Date: 14-Nov-2005

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<b><i>Arthropathies NEC</i></b>		
Arthritis	11	0
Arthropathy	1	0
Haemarthrosis	1	0
SLE arthritis	1	0
<b><i>Bone related signs and symptoms</i></b>		
Bone pain	1	0
Pain in jaw	1	0
<b><i>Connective tissue disorders NEC</i></b>		
Polymyalgia rheumatica	1	0
<b><i>Intervertebral disc disorders NEC</i></b>		
Intervertebral disc protrusion	2	0
<b><i>Joint related disorders NEC</i></b>		
Periarthritis	1	0
Rotator cuff syndrome	1	0
<b><i>Joint related signs and symptoms</i></b>		
Arthralgia	230	0
Joint stiffness	9	0
Joint swelling	11	1
<b><i>Lupus erythematosus (incl subtypes)</i></b>		
Lupus-like syndrome	1	0
<b><i>Muscle infections and inflammations</i></b>		
Myositis	3	0
Polymyositis	1	0
<b><i>Muscle pains</i></b>		
Fibromyalgia	6	0
Myalgia	262	0
<b><i>Muscle related signs and symptoms NEC</i></b>		
Muscle discomfort	1	0
Muscle disorder	3	0
Muscle fatigue	1	0
Muscle spasms	17	0
Muscle swelling	2	0
Muscle tightness	1	0
Muscle twitching	7	0
<b><i>Muscle tone abnormalities</i></b>		
Floppy infant	1	0
Muscle rigidity	1	0
Nuchal rigidity	1	0
Torticollis	1	0
<b><i>Muscle weakness conditions</i></b>		
Muscular weakness	36	0
<b><i>Musculoskeletal and connective tissue conditions NEC</i></b>		
Mobility decreased	2	0
Musculoskeletal stiffness	51	0
<b><i>Musculoskeletal and connective tissue pain and discomfort</i></b>		
Back pain	39	0
Limb discomfort	74	0
Musculoskeletal chest pain	2	0
Musculoskeletal discomfort	8	0
Musculoskeletal pain	2	0
Neck pain	28	0
Pain in extremity	319	0

## Case Series Drug Analysis Print

### Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023

Data Lock Date: 24-Feb-2023 18:30:04

Earliest Reaction Date: 14-Nov-2005

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Muscle &amp; tissue disorders cont'd</i>		
<b><i>Myopathies</i></b>		
Rhabdomyolysis	2	1
<b><i>Psoriatic arthropathies</i></b>		
Psoriatic arthropathy	1	0
<b><i>Rheumatoid arthropathies</i></b>		
Rheumatoid arthritis	5	0
<b><i>Soft tissue disorders NEC</i></b>		
Axillary mass	1	0
Groin pain	3	0
<b><i>Spondyloarthropathies</i></b>		
Arthritis reactive	3	0
<b><i>Tendon disorders</i></b>		
Tendonitis	3	0
Tenosynovitis	2	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>1161</b>	<b>2</b>

# Case Series Drug Analysis Print

## Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023

Data Lock Date: 24-Feb-2023 18:30:04

Earliest Reaction Date: 14-Nov-2005

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i>Renal neoplasms malignant</i>		
Renal cancer recurrent	1	0
<i>Skin neoplasms benign</i>		
Seborrhoeic keratosis	1	0
<b>Neoplasms SOC TOTAL</b>	<b>2</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023

Data Lock Date: 24-Feb-2023 18:30:04

Earliest Reaction Date: 14-Nov-2005

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Abnormal reflexes</i>		
Areflexia	1	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	7	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	13	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebral haemorrhage	2	2
<i>Chronic polyneuropathies</i>		
Chronic inflammatory demyelinating polyradiculoneuropathy	1	0
<i>Coma states</i>		
Coma	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	11	0
Coordination abnormal	3	0
Dysstasia	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	2	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	1	0
Depressed level of consciousness	1	0
Lethargy	88	0
Loss of consciousness	14	0
Sedation	1	0
Somnolence	62	0
Syncope	34	0
<i>Disturbances in sleep phase rhythm</i>		
Non-24-hour sleep-wake disorder	1	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	3	0
Hypokinesia	6	0
Psychomotor hyperactivity	3	0
<i>Encephalopathies NEC</i>		
Encephalopathy	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	5	0
Facial paralysis	2	0
Facial paresis	1	0
Facial spasm	1	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	6	0
<i>Headaches NEC</i>		
Cluster headache	2	0
Headache	532	0
Sinus headache	2	0
Tension headache	8	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Sciatica	1	0
<i>Memory loss (excl dementia)</i>		
Amnesia	7	0
Memory impairment	6	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	1	0

## Case Series Drug Analysis Print

### Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023

Data Lock Date: 24-Feb-2023 18:30:04

Earliest Reaction Date: 14-Nov-2005

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Disturbance in attention	13	0
<b>Migraine headaches</b>		
Hemiplegic migraine	1	0
Migraine	30	0
Ophthalmic migraine	1	0
<b>Motor neurone diseases</b>		
Motor neurone disease	1	0
<b>Muscle tone abnormal</b>		
Hypotonia	1	0
<b>Myelitis (incl infective)</b>		
Myelitis transverse	6	0
<b>Narcolepsy and hypersomnia</b>		
Cataplexy	100	0
Hypersomnia	16	0
Narcolepsy	123	0
<b>Nervous system disorders NEC</b>		
Nervous system disorder	2	0
<b>Neurological signs and symptoms NEC</b>		
Clonus	1	0
Dizziness	172	0
Dizziness postural	6	0
Fontanelle bulging	1	0
Head discomfort	16	0
Myoclonus	1	0
Neurological symptom	4	0
Presyncope	7	0
Unresponsive to stimuli	1	0
<b>Neuromuscular disorders NEC</b>		
Muscle contractions involuntary	3	0
Muscle spasticity	3	0
<b>Neuromuscular junction dysfunction</b>		
Myasthenia gravis	1	0
<b>Olfactory nerve disorders</b>		
Anosmia	1	0
<b>Optic nerve disorders NEC</b>		
Optic neuritis	1	0
<b>Paraesthesias and dysaesthesias</b>		
Burning sensation	12	0
Hyperaesthesia	4	0
Hypoaesthesia	55	0
Paraesthesia	120	0
<b>Paralysis and paresis (excl cranial nerve)</b>		
Hemiparesis	1	0
Hemiplegia	1	0
Monoplegia	3	0
Paralysis	8	0
<b>Partial complex seizures</b>		
Dreamy state	2	0
<b>Partial simple seizures NEC</b>		
Simple partial seizures	1	0
<b>Peripheral neuropathies NEC</b>		
Neuropathy peripheral	3	0
Peripheral sensorimotor neuropathy	1	0

## Case Series Drug Analysis Print

### Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023

Data Lock Date: 24-Feb-2023 18:30:04

Earliest Reaction Date: 14-Nov-2005

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small>		
<b><i>Seizures and seizure disorders NEC</i></b>		
Convulsion in childhood	1	0
Epilepsy	6	2
Febrile convulsion	10	0
Neonatal seizure	1	0
Seizure	17	0
<b><i>Sensory abnormalities NEC</i></b>		
Ageusia	1	0
Dysgeusia	14	0
Neuralgia	8	0
Sensory disturbance	2	0
Sensory loss	5	0
Taste disorder	1	0
<b><i>Sleep disturbances NEC</i></b>		
Sudden onset of sleep	5	0
<b><i>Speech and language abnormalities</i></b>		
Dysarthria	4	0
Speech disorder	6	0
<b><i>Spinal cord and nerve root disorders NEC</i></b>		
Radiculitis brachial	1	0
<b><i>Transient cerebrovascular events</i></b>		
Transient ischaemic attack	1	0
<b><i>Tremor (excl congenital)</i></b>		
Head titubation	1	0
Tremor	36	0
<b><i>Trigeminal disorders</i></b>		
Trigeminal nerve paresis	1	0
Trigeminal neuralgia	5	0
<b>Nervous system disorders SOC TOTAL</b>	<b>1680</b>	<b>4</b>

## Case Series Drug Analysis Print

### Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023

Data Lock Date: 24-Feb-2023 18:30:04

Earliest Reaction Date: 14-Nov-2005

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i>Abortions not specified as induced or spontaneous</i>		
Abortion missed	1	0
<i>Abortions spontaneous</i>		
Abortion spontaneous	26	0
<i>Foetal complications NEC</i>		
Foetal hypokinesia	2	0
<i>Foetal growth complications</i>		
Foetal growth restriction	2	0
<i>Foetal position and presentation abnormalities</i>		
Face presentation	1	0
<i>Labour onset and length abnormalities</i>		
Premature delivery	1	0
Threatened labour	1	0
<i>Maternal complications of pregnancy NEC</i>		
Morning sickness	5	0
<i>Normal pregnancy, labour and delivery</i>		
Live birth	5	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	1	0
<i>Stillbirth and foetal death</i>		
Foetal death	3	3
Stillbirth	3	3
<i>Unintended pregnancies</i>		
Unintended pregnancy	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>52</b>	<b>6</b>

## Case Series Drug Analysis Print

### Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023  
Earliest Reaction Date: 14-Nov-2005

Data Lock Date: 24-Feb-2023 18:30:04  
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	6	0
Behaviour disorder	1	0
<b><i>Affect alterations NEC</i></b>		
Affect lability	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	2	0
Anxiety	8	0
Nervousness	6	0
<b><i>Attention deficit and disruptive behaviour disorders</i></b>		
Attention deficit hyperactivity disorder	1	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Aggression	6	0
Paranoia	1	0
Personality change	2	0
Social avoidant behaviour	1	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	8	0
Disorientation	7	0
<b><i>Deliria</i></b>		
Delirium	7	0
<b><i>Delusional symptoms</i></b>		
Delusion	1	0
Mixed delusion	1	0
<b><i>Depressive disorders</i></b>		
Agitated depression	1	0
Depression	10	0
<b><i>Dissociative states</i></b>		
Depersonalisation/derealisation disorder	1	0
Dissociation	3	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Insomnia	36	0
Middle insomnia	1	0
<b><i>Eating disorders NEC</i></b>		
Eating disorder	1	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Anger	7	0
Emotional disorder	4	0
Emotional distress	7	0
Frustration tolerance decreased	3	0
Irritability	2	0
Mood altered	4	0
<b><i>Fear symptoms and phobic disorders (incl social phobia)</i></b>		
Fear	5	0
<b><i>Fluctuating mood symptoms</i></b>		
Mood swings	4	0
<b><i>Hallucinations (excl sleep-related)</i></b>		
Hallucination	16	0
Hallucination, auditory	1	0
Hallucination, visual	1	0
<b><i>Increased physical activity levels</i></b>		
Restlessness	5	0
<b><i>Learning disorders</i></b>		

## Case Series Drug Analysis Print

### Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023

Data Lock Date: 24-Feb-2023 18:30:04

Earliest Reaction Date: 14-Nov-2005

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Learning disorder	1	0
<b>Mental disorders NEC</b>		
Mental disorder	1	0
<b>Mood alterations with depressive symptoms</b>		
Depressed mood	9	0
Tearfulness	2	0
<b>Mood alterations with manic symptoms</b>		
Hypomania	1	0
<b>Mood disorders NEC</b>		
Listless	3	0
<b>Narcolepsy and associated conditions</b>		
Hypnagogic hallucination	4	0
Sleep attacks	1	0
<b>Panic attacks and disorders</b>		
Panic attack	2	0
Panic reaction	1	0
<b>Parasomnias</b>		
Abnormal dreams	9	0
Nightmare	13	0
Parasomnia	1	0
Rapid eye movements sleep abnormal	1	0
Sleep terror	4	0
<b>Pervasive developmental disorders NEC</b>		
Autism spectrum disorder	2	0
<b>Psychiatric symptoms NEC</b>		
Psychiatric symptom	3	0
<b>Psychotic disorder NEC</b>		
Psychotic disorder	3	0
<b>Sleep disorders NEC</b>		
Sleep disorder	27	0
<b>Stereotypies and automatisms</b>		
Head banging	5	0
Waxy flexibility	1	0
<b>Suicidal and self-injurious behaviour</b>		
Completed suicide	1	0
Suicidal ideation	1	0
Suicide attempt	2	0
<b>Thinking disturbances</b>		
Thinking abnormal	1	0
<b>Tic disorders</b>		
Tic	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>271</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023  
 Earliest Reaction Date: 14-Nov-2005

Data Lock Date: 24-Feb-2023 18:30:04  
 MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i><b>Bladder and urethral symptoms</b></i>		
Bladder irritation	1	0
Incontinence	1	0
Pollakiuria	1	0
Urinary incontinence	1	0
<i><b>Bladder disorders NEC</b></i>		
Urinary bladder haemorrhage	1	0
<i><b>Myoneurogenic bladder disorders</b></i>		
Neurogenic bladder	1	0
<i><b>Nephritis NEC</b></i>		
Tubulointerstitial nephritis	1	0
<i><b>Renal disorders NEC</b></i>		
Renal disorder	1	0
<i><b>Renal failure and impairment</b></i>		
Acute kidney injury	7	0
Chronic kidney disease	1	0
Renal failure	1	0
<i><b>Urinary abnormalities</b></i>		
Haematuria	2	0
<i><b>Urinary tract signs and symptoms NEC</b></i>		
Nocturia	1	0
Polyuria	1	0
Renal pain	7	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>28</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023

Data Lock Date: 24-Feb-2023 18:30:04

Earliest Reaction Date: 14-Nov-2005

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Breast signs and symptoms</b></i>		
Breast pain	5	0
Breast swelling	1	0
<i><b>Menstruation and uterine bleeding NEC</b></i>		
Intermenstrual bleeding	1	0
<i><b>Menstruation with decreased bleeding</b></i>		
Amenorrhoea	1	0
<i><b>Ovarian and fallopian tube cysts and neoplasms</b></i>		
Polycystic ovaries	1	0
<i><b>Reproductive tract signs and symptoms NEC</b></i>		
Genital pain	1	0
Pelvic pain	1	0
<i><b>Vulvovaginal disorders NEC</b></i>		
Vaginal haemorrhage	4	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>15</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023

Data Lock Date: 24-Feb-2023 18:30:04

Earliest Reaction Date: 14-Nov-2005

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Dyspnoea	62	0
Dyspnoea exertional	1	0
Hyperventilation	1	0
Hypopnoea	2	0
Obstructive sleep apnoea syndrome	1	0
Sleep apnoea syndrome	1	0
Tachypnoea	2	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	24	0
Bronchial obstruction	1	0
Bronchospasm	3	0
Chronic obstructive pulmonary disease	2	0
Cough variant asthma	1	0
Obstructive airways disorder	2	0
Wheezing	19	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	66	0
Haemoptysis	1	0
Productive cough	11	0
<i><b>Laryngeal spasm, oedema and obstruction</b></i>		
Stridor	1	0
<i><b>Lower respiratory tract inflammatory and immunologic conditions</b></i>		
Pneumonitis	1	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	4	0
Nasal inflammation	1	0
Rhinitis allergic	1	0
Rhinitis perennial	1	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	9	0
<i><b>Paranasal sinus disorders (excl infections and neoplasms)</b></i>		
Sinus congestion	5	0
Sinus disorder	1	0
<i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>		
Pharyngeal hypoaesthesia	2	0
Pharyngeal swelling	2	0
Tonsillar disorder	1	0
<i><b>Pleural infections and inflammations</b></i>		
Pleurisy	1	0
<i><b>Pulmonary oedemas</b></i>		
Acute respiratory distress syndrome	1	0
<i><b>Pulmonary thrombotic and embolic conditions</b></i>		
Pulmonary embolism	1	1
<i><b>Respiratory failures (excl neonatal)</b></i>		
Respiratory failure	1	1
<i><b>Respiratory signs and symptoms NEC</b></i>		
Pleural rub	1	0
<i><b>Respiratory tract disorders NEC</b></i>		
Respiratory tract congestion	3	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Aphonia	3	0
Catarrh	2	0

# Case Series Drug Analysis Print

## Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023

Data Lock Date: 24-Feb-2023 18:30:04

Earliest Reaction Date: 14-Nov-2005

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b> Respiratory disorders cont'd		
Choking	1	0
Dry throat	1	0
Dysphonia	3	0
Oropharyngeal pain	89	0
Rhinorrhoea	46	0
Sinus pain	4	0
Sneezing	18	0
Throat irritation	3	0
Throat tightness	7	0
Upper-airway cough syndrome	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>415</b>	<b>2</b>

## Case Series Drug Analysis Print

### Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023

Data Lock Date: 24-Feb-2023 18:30:04

Earliest Reaction Date: 14-Nov-2005

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<i><b>Alopecias</b></i>		
Alopecia	1	0
Alopecia areata	1	0
Alopecia universalis	1	0
<i><b>Angioedemas</b></i>		
Angioedema	2	0
<i><b>Apocrine and eccrine gland disorders</b></i>		
Cold sweat	8	0
Hyperhidrosis	56	0
Hypohidrosis	1	0
Night sweats	7	0
<i><b>Bullous conditions</b></i>		
Blister	8	0
Erythema multiforme	6	0
Pemphigoid	1	0
Stevens-Johnson syndrome	2	0
Toxic epidermal necrolysis	1	1
<i><b>Dermal and epidermal conditions NEC</b></i>		
Pain of skin	4	0
Skin discolouration	6	0
Skin discomfort	2	0
Skin disorder	1	0
Skin lesion	2	0
Skin reaction	13	0
Skin warm	3	0
<i><b>Dermatitis and eczema</b></i>		
Dermatitis	5	0
Dermatitis allergic	6	0
Eczema	3	0
Skin irritation	5	0
<i><b>Dermatitis ascribed to specific agent</b></i>		
Palmar-plantar erythrodysesthesia syndrome	1	0
<i><b>Erythemas</b></i>		
Erythema	45	0
<i><b>Exfoliative conditions</b></i>		
Exfoliative rash	1	0
Skin exfoliation	1	0
<i><b>Granulomatous and deep cutaneous inflammatory conditions</b></i>		
Granuloma annulare	1	0
<i><b>Panniculitides</b></i>		
Erythema nodosum	2	0
<i><b>Papulosquamous conditions</b></i>		
Pityriasis rosea	1	0
<i><b>Photosensitivity and photodermatitis conditions</b></i>		
Photosensitivity reaction	2	0
<i><b>Pruritus NEC</b></i>		
Pruritus	51	0
<i><b>Psoriatic conditions</b></i>		
Guttate psoriasis	1	0
<i><b>Purpura and related conditions</b></i>		
Petechiae	1	0
Purpura	8	0
<i><b>Rashes, eruptions and exanthems NEC</b></i>		

## Case Series Drug Analysis Print

### Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023

Data Lock Date: 24-Feb-2023 18:30:04

Earliest Reaction Date: 14-Nov-2005

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Rash	126	0
Rash erythematous	18	0
Rash macular	13	0
Rash maculo-papular	10	0
Rash morbilliform	1	0
Rash papular	5	0
Rash pruritic	12	0
<b><i>Skin and subcutaneous tissue ulcerations</i></b>		
Skin ulcer	1	0
<b><i>Skin vasculitides</i></b>		
Vasculitic rash	1	0
<b><i>Urticarias</i></b>		
Mechanical urticaria	1	0
Urticaria	56	0
Urticaria papular	3	0
<b>Skin disorders SOC TOTAL</b>	<b>507</b>	<b>1</b>

## Case Series Drug Analysis Print

### Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023

Data Lock Date: 24-Feb-2023 18:30:04

Earliest Reaction Date: 14-Nov-2005

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i><b>Dependents</b></i>		
Sick relative	1	0
<i><b>Disability issues</b></i>		
Bedridden	1	0
Disability	1	0
Impaired driving ability	2	0
Impaired work ability	1	0
Loss of personal independence in daily activities	4	0
Walking aid user	1	0
Wheelchair user	2	0
<i><b>Educational issues</b></i>		
Educational problem	3	0
<i><b>Employment issues</b></i>		
Loss of employment	1	0
<i><b>Family and partner issues</b></i>		
Family stress	2	0
<i><b>Social issues NEC</b></i>		
Social problem	3	0
<b>Social circumstances SOC TOTAL</b>	<b>22</b>	<b>0</b>

# Case Series Drug Analysis Print

## Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023

Data Lock Date: 24-Feb-2023 18:30:04

Earliest Reaction Date: 14-Nov-2005

MedDRA Version: MedDRA 25.1

<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Surgical &amp; medical procedures</b>		
<i>Blood and blood product treatment</i>		
Plasmapheresis	1	0
<i>Joint therapeutic procedures</i>		
Knee arthroplasty	1	0
<i>Therapeutic procedures NEC</i>		
Anaphylaxis treatment	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>3</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 23/124 - Pandemrix Vaccine Analysis Print

Report Run Date: 02-Mar-2023

Data Lock Date: 24-Feb-2023 18:30:04

Earliest Reaction Date: 14-Nov-2005

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i>Arterial infections and inflammations</i>		
Giant cell arteritis	1	0
Kawasaki's disease	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	21	0
Neurogenic shock	1	0
Peripheral circulatory failure	2	0
<i>Haemorrhages NEC</i>		
Haemorrhage	2	0
<i>Peripheral embolism and thrombosis</i>		
Thrombophlebitis	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	3	0
Flushing	14	0
Hot flush	14	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral arterial occlusive disease	1	0
Peripheral coldness	13	0
Raynaud's phenomenon	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	11	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	7	0
<i>Vascular hypotensive disorders</i>		
Hypotension	11	0
<i>Vasculitides NEC</i>		
Vasculitis	3	0
<b>Vascular disorders SOC TOTAL</b>	<b>107</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>8510</b>	<b>34</b>
<b>TOTAL REPORTS</b>	<b>3145</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>34</b>