

## Case Series Drug Analysis Print

**Name: Pandemrix**

Report Run Date: 01-Dec-2014  
Data Lock Date: 28-Nov-2014 19:00:07  
Earliest Reaction Date: 07-Nov-2008  
MedDRA Version: MedDRA 17.1  
Pandemrix: Alle spontane cases, Pandemrix

# Case Series Drug Analysis Print

Name: Pandemrix

Report Run Date: 01-Dec-2014  
Earliest Reaction Date: 07-Nov-2008

Data Lock Date: 28-Nov-2014 19:00:07  
MedDRA Version: MedDRA 17.1

Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	3	0
Lymphadenitis	1	0
Lymphadenopathy	12	0
<b>Blood disorders SOC TOTAL</b>	<b>16</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: Pandemrix

Report Run Date: 01-Dec-2014  
Earliest Reaction Date: 07-Nov-2008

Data Lock Date: 28-Nov-2014 19:00:07  
MedDRA Version: MedDRA 17.1

Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i><b>Cardiac disorders NEC</b></i>		
Cardiac disorder	1	0
<i><b>Cardiac signs and symptoms NEC</b></i>		
Cyanosis	1	0
Palpitations	7	0
<i><b>Heart failures NEC</b></i>		
Cardiac failure	1	0
Cardiopulmonary failure	1	1
<i><b>Ischaemic coronary artery disorders</b></i>		
Angina pectoris	1	0
<i><b>Noninfectious pericarditis</b></i>		
Pericarditis	1	0
<i><b>Rate and rhythm disorders NEC</b></i>		
Extrasystoles	1	0
Tachycardia	1	0
<i><b>Supraventricular arrhythmias</b></i>		
Atrial fibrillation	2	0
<i><b>Ventricular arrhythmias and cardiac arrest</b></i>		
Cardiac arrest	1	0
Ventricular fibrillation	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>19</b>	<b>1</b>

# Case Series Drug Analysis Print

Name: Pandemrix

Report Run Date: 01-Dec-2014  
Earliest Reaction Date: 07-Nov-2008

Data Lock Date: 28-Nov-2014 19:00:07  
MedDRA Version: MedDRA 17.1

Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Cerebral disorders congenital</i>		
Cerebral palsy	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: Pandemrix

Report Run Date: 01-Dec-2014  
Earliest Reaction Date: 07-Nov-2008

Data Lock Date: 28-Nov-2014 19:00:07  
MedDRA Version: MedDRA 17.1

Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear pain	2	0
<i>Hearing losses</i>		
Sudden hearing loss	1	0
<i>Hyperacusia</i>		
Hyperacusis	2	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	3	0
<b>Ear disorders SOC TOTAL</b>	<b>8</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: Pandemrix

Report Run Date: 01-Dec-2014  
Earliest Reaction Date: 07-Nov-2008

Data Lock Date: 28-Nov-2014 19:00:07  
MedDRA Version: MedDRA 17.1

Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i>Lacrimation disorders</i>		
Lacrimation increased	2	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Eyelid oedema	2	0
<i>Ocular disorders NEC</i>		
Eye pain	2	0
Eye swelling	2	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Ocular hyperaemia	1	0
<i>Ocular nerve and muscle disorders</i>		
Binocular eye movement disorder	1	0
<i>Ocular sensation disorders</i>		
Photophobia	6	0
<i>Pupil disorders</i>		
Mydriasis	1	0
Pupil fixed	1	0
Pupils unequal	1	0
<i>Visual disorders NEC</i>		
Vision blurred	2	0
Visual impairment	4	0
<b>Eye disorders SOC TOTAL</b>	<b>25</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: Pandemrix

Report Run Date: 01-Dec-2014  
Earliest Reaction Date: 07-Nov-2008

Data Lock Date: 28-Nov-2014 19:00:07  
MedDRA Version: MedDRA 17.1

Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Anal and rectal signs and symptoms</i>		
Rectal discharge	1	0
<i>Colitis (excl infective)</i>		
Colitis microscopic	1	0
Colitis ulcerative	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	38	0
Diarrhoea haemorrhagic	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	2	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	21	0
Abdominal pain lower	1	0
Abdominal pain upper	10	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	1	0
<i>Gastrointestinal disorders NEC</i>		
Gastric disorder	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	1	0
Dysphagia	1	0
Faecal incontinence	2	0
<i>Nausea and vomiting symptoms</i>		
Nausea	74	0
Vomiting	36	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematemesis	1	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	2	0
<i>Oral soft tissue pain and paraesthesia</i>		
Paraesthesia oral	5	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	1	0
Oral discomfort	1	0
Oral mucosal blistering	1	0
Oral pruritus	2	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	2	0
Mouth swelling	1	0
Oedema mouth	1	0
<i>Rectal inflammations NEC</i>		
Proctitis haemorrhagic	1	0
<i>Stomatitis and ulceration</i>		
Stomatitis	1	0
<i>Tongue signs and symptoms</i>		
Swollen tongue	5	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>216</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: Pandemrix

Report Run Date: 01-Dec-2014  
Earliest Reaction Date: 07-Nov-2008

Data Lock Date: 28-Nov-2014 19:00:07  
MedDRA Version: MedDRA 17.1

Reaction Name	Total	Fatal
<b>General disorders</b>		
<i><b>Asthenic conditions</b></i>		
Asthenia	18	0
Chronic fatigue syndrome	1	0
Fatigue	86	0
Malaise	81	0
<i><b>Death and sudden death</b></i>		
Sudden death	2	2
<i><b>Febrile disorders</b></i>		
Pyrexia	142	0
<i><b>Feelings and sensations NEC</b></i>		
Chills	20	0
Feeling abnormal	7	0
Feeling cold	7	0
Feeling hot	11	0
Feeling of body temperature change	4	0
Sense of oppression	2	0
Thirst	2	0
<i><b>Gait disturbances</b></i>		
Gait disturbance	3	0
<i><b>General signs and symptoms NEC</b></i>		
Condition aggravated	2	0
Crepitations	1	0
Crying	1	0
General physical health deterioration	1	0
Ill-defined disorder	1	0
Influenza like illness	33	0
Local reaction	2	0
Local swelling	6	0
Peripheral swelling	21	0
Swelling	9	0
<i><b>Injection site reactions</b></i>		
Injected limb mobility decreased	3	0
Injection site discharge	1	0
Injection site discolouration	1	0
Injection site discomfort	1	0
Injection site eczema	2	0
Injection site erythema	28	0
Injection site haematoma	2	0
Injection site induration	2	0
Injection site inflammation	2	0
Injection site joint pain	1	0
Injection site joint redness	1	0
Injection site lymphadenopathy	1	0
Injection site mass	1	0
Injection site movement impairment	1	0
Injection site nodule	4	0
Injection site pain	63	0
Injection site papule	1	0
Injection site paraesthesia	1	0
Injection site pruritus	7	0
Injection site rash	4	0
Injection site reaction	2	0
Injection site swelling	40	0



# Case Series Drug Analysis Print

Name: Pandemrix

Report Run Date: 01-Dec-2014  
Earliest Reaction Date: 07-Nov-2008

Data Lock Date: 28-Nov-2014 19:00:07  
MedDRA Version: MedDRA 17.1

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Injection site ulcer	1	0
Injection site urticaria	3	0
Injection site warmth	8	0
<b>Interactions</b>		
Drug interaction	1	0
<b>Oedema NEC</b>		
Face oedema	1	0
Generalised oedema	1	0
Localised oedema	2	0
Oedema peripheral	1	0
<b>Pain and discomfort NEC</b>		
Axillary pain	2	0
Chest discomfort	7	0
Chest pain	9	0
Discomfort	13	0
Facial pain	1	0
Pain	28	0
Tenderness	21	0
<b>Therapeutic and nontherapeutic responses</b>		
Adverse reaction	1	0
<b>Trophic disorders</b>		
Atrophy	1	0
<b>Vaccination site reactions</b>		
Extensive swelling of vaccinated limb	1	0
Vaccination site pain	2	0
<b>General disorders SOC TOTAL</b>	<b>736</b>	<b>2</b>

## Case Series Drug Analysis Print

Name: Pandemrix

Report Run Date: 01-Dec-2014  
Earliest Reaction Date: 07-Nov-2008

Data Lock Date: 28-Nov-2014 19:00:07  
MedDRA Version: MedDRA 17.1

Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	2	0
<b>Hepatic disorders SOC TOTAL</b>	<b>2</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: Pandemrix

Report Run Date: 01-Dec-2014  
Earliest Reaction Date: 07-Nov-2008

Data Lock Date: 28-Nov-2014 19:00:07  
MedDRA Version: MedDRA 17.1

Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Allergic conditions NEC</i>		
Hypersensitivity	4	0
<i>Anaphylactic responses</i>		
Anaphylactic reaction	5	0
Anaphylactic shock	3	0
<i>Transplant rejections</i>		
Transplant rejection	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>13</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: Pandemrix

Report Run Date: 01-Dec-2014  
Earliest Reaction Date: 07-Nov-2008

Data Lock Date: 28-Nov-2014 19:00:07  
MedDRA Version: MedDRA 17.1

Reaction Name	Total	Fatal
<b>Infections</b>		
<i>Abdominal and gastrointestinal infections</i>		
Gastroenteritis	1	0
<i>Central nervous system and spinal infections</i>		
Encephalomyelitis	2	0
<i>Ear infections</i>		
Otitis media	1	0
<i>Herpes viral infections</i>		
Herpes zoster	3	0
Oral herpes	1	0
<i>Infections NEC</i>		
Infection	1	0
Injection site infection	1	0
<i>Influenza viral infections</i>		
Influenza	4	0
<i>Lower respiratory tract and lung infections</i>		
Pneumonia	9	3
<i>Streptococcal infections</i>		
Pneumonia pneumococcal	1	0
<i>Upper respiratory tract infections</i>		
Laryngitis	1	0
Nasopharyngitis	3	0
Upper respiratory tract infection	1	0
<i>Viral infections NEC</i>		
Gastroenteritis viral	1	0
<b>Infections SOC TOTAL</b>	<b>30</b>	<b>3</b>

# Case Series Drug Analysis Print

Name: Pandemrix

Report Run Date: 01-Dec-2014  
Earliest Reaction Date: 07-Nov-2008

Data Lock Date: 28-Nov-2014 19:00:07  
MedDRA Version: MedDRA 17.1

Reaction Name	Total	Fatal
<b>Injuries</b>		
<i>Accidental exposures to product</i>		
Accidental exposure to product	1	0
<i>Chest and lung injuries NEC</i>		
Tracheal obstruction	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	4	0
Foetal exposure during pregnancy	1	0
<i>Non-site specific injuries NEC</i>		
Fall	4	0
<i>Transplantation complications</i>		
Complications of transplanted kidney	3	0
<b>Injuries SOC TOTAL</b>	<b>14</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: Pandemrix

Report Run Date: 01-Dec-2014  
Earliest Reaction Date: 07-Nov-2008

Data Lock Date: 28-Nov-2014 19:00:07  
MedDRA Version: MedDRA 17.1

Reaction Name	Total	Fatal
<b>Investigations</b>		
<i><b>Carbohydrate tolerance analyses (incl diabetes)</b></i>		
Blood glucose increased	2	0
<i><b>Heart rate and pulse investigations</b></i>		
Heart rate increased	2	0
Pulse absent	1	0
<i><b>Investigations NEC</b></i>		
Quality of life decreased	1	0
<i><b>Physical examination procedures and organ system status</b></i>		
Body temperature increased	1	0
Breath sounds abnormal	1	0
Weight decreased	5	0
Weight increased	2	0
<i><b>Protein analyses NEC</b></i>		
C-reactive protein increased	2	0
<i><b>Renal function analyses</b></i>		
Blood creatinine increased	1	0
<i><b>Respiratory and pulmonary function diagnostic procedures</b></i>		
Peak expiratory flow rate decreased	1	0
Pulmonary function test abnormal	1	0
Total lung capacity decreased	1	0
<i><b>Skeletal and cardiac muscle analyses</b></i>		
Blood creatine phosphokinase increased	1	0
<i><b>Tissue enzyme analyses NEC</b></i>		
Blood lactate dehydrogenase increased	1	0
<i><b>Vascular tests NEC (incl blood pressure)</b></i>		
Blood pressure increased	1	0
<b>Investigations SOC TOTAL</b>	<b>24</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: Pandemrix

Report Run Date: 01-Dec-2014  
Earliest Reaction Date: 07-Nov-2008

Data Lock Date: 28-Nov-2014 19:00:07  
MedDRA Version: MedDRA 17.1

Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Decreased appetite	13	0
<i><b>Total fluid volume increased</b></i>		
Fluid retention	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>14</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: Pandemrix

Report Run Date: 01-Dec-2014  
Earliest Reaction Date: 07-Nov-2008

Data Lock Date: 28-Nov-2014 19:00:07  
MedDRA Version: MedDRA 17.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i><b>Arthropathies NEC</b></i>		
Arthritis	2	0
Arthritis reactive	1	0
Arthropathy	2	0
Polyarthritis	1	0
Seronegative arthritis	1	0
<i><b>Bone related signs and symptoms</b></i>		
Bone pain	1	0
Pain in jaw	1	0
<i><b>Connective tissue disorders NEC</b></i>		
Polymyalgia rheumatica	2	0
<i><b>Joint related disorders NEC</b></i>		
Periarthritis	5	0
Rotator cuff syndrome	1	0
<i><b>Joint related signs and symptoms</b></i>		
Arthralgia	50	0
Joint range of motion decreased	1	0
Joint swelling	1	0
<i><b>Muscle pains</b></i>		
Fibromyalgia	1	0
Myalgia	74	0
<i><b>Muscle related signs and symptoms NEC</b></i>		
Muscle atrophy	3	0
Muscle fatigue	1	0
Muscle spasms	17	0
Muscle swelling	1	0
Muscle twitching	2	0
<i><b>Muscle weakness conditions</b></i>		
Muscular weakness	15	0
<i><b>Musculoskeletal and connective tissue pain and discomfort</b></i>		
Back pain	10	0
Flank pain	1	0
Limb discomfort	2	0
Musculoskeletal discomfort	2	0
Musculoskeletal pain	23	0
Neck pain	12	0
Pain in extremity	60	0
<i><b>Musculoskeletal and connective tissue signs and symptoms NEC</b></i>		
Mobility decreased	3	0
Musculoskeletal disorder	1	0
Musculoskeletal stiffness	9	0
<i><b>Myopathies</b></i>		
Rhabdomyolysis	1	0
<i><b>Rheumatoid arthropathies</b></i>		
Rheumatoid arthritis	2	0
<i><b>Soft tissue disorders NEC</b></i>		
Groin pain	2	0
<i><b>Spine and neck deformities</b></i>		
Scoliosis	1	0
<i><b>Tendon disorders</b></i>		
Enthesopathy	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>313</b>	<b>0</b>



# Case Series Drug Analysis Print

Name: Pandemrix

Report Run Date: 01-Dec-2014  
Earliest Reaction Date: 07-Nov-2008

Data Lock Date: 28-Nov-2014 19:00:07  
MedDRA Version: MedDRA 17.1

Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i>Respiratory tract and pleural neoplasms malignant cell type unspecified</i>		
<b>NEC</b>		
Lung cancer metastatic	1	1
<b>Neoplasms SOC TOTAL</b>	<b>1</b>	<b>1</b>

# Case Series Drug Analysis Print

Name: Pandemrix

Report Run Date: 01-Dec-2014  
Earliest Reaction Date: 07-Nov-2008

Data Lock Date: 28-Nov-2014 19:00:07  
MedDRA Version: MedDRA 17.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Abnormal reflexes</i>		
Hyporeflexia	1	0
<i>Absence seizures</i>		
Petit mal epilepsy	1	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	5	0
Polyneuropathy	2	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebral infarction	2	0
Intraventricular haemorrhage neonatal	1	0
<i>Chronic polyneuropathies</i>		
Demyelinating polyneuropathy	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	1	0
Balance disorder	3	0
Coordination abnormal	4	0
<i>Disturbances in consciousness NEC</i>		
Loss of consciousness	2	0
Somnolence	7	0
Syncope	4	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	1	0
Hypokinesia	2	0
Movement disorder	1	0
<i>Facial cranial nerve disorders</i>		
Facial paresis	2	0
VIIth nerve paralysis	1	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	1	0
<i>Headaches NEC</i>		
Headache	112	0
<i>Memory loss (excl dementia)</i>		
Amnesia	1	0
Memory impairment	3	0
Retrograde amnesia	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	2	0
Disturbance in attention	3	0
<i>Migraine headaches</i>		
Migraine	5	0
<i>Mononeuropathies</i>		
Carpal tunnel syndrome	1	0
Peroneal nerve palsy	1	0
<i>Multiple sclerosis acute and progressive</i>		
Multiple sclerosis	2	0
<i>Muscle tone abnormal</i>		
Hypertonia	1	0
<i>Narcolepsy and hypersomnia</i>		
Cataplexy	3	0
Hypersomnia	1	0
Narcolepsy	3	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	74	0

# Case Series Drug Analysis Print

Name: Pandemrix

Report Run Date: 01-Dec-2014  
Earliest Reaction Date: 07-Nov-2008

Data Lock Date: 28-Nov-2014 19:00:07  
MedDRA Version: MedDRA 17.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Dizziness postural	1	0
Head discomfort	3	0
Presyncope	5	0
Unresponsive to stimuli	1	0
<b>Neuromuscular disorders NEC</b>		
Muscle contractions involuntary	2	0
Muscle spasticity	1	0
<b>Olfactory nerve disorders</b>		
Hyposmia	1	0
<b>Paraesthesias and dysaesthesias</b>		
Burning sensation	7	0
Dysaesthesia	2	0
Hyperaesthesia	1	0
Hypoaesthesia	15	0
Paraesthesia	32	0
<b>Paralysis and paresis (excl cranial nerve)</b>		
Hemiparesis	1	0
Monoparesis	1	0
Monoplegia	2	0
<b>Parkinson's disease and parkinsonism</b>		
Parkinsonism	1	0
<b>Peripheral neuropathies NEC</b>		
Neuritis	2	0
Neuropathy peripheral	4	0
<b>Seizures and seizure disorders NEC</b>		
Convulsion	5	0
Epilepsy	2	0
Febrile convulsion	1	0
<b>Sensory abnormalities NEC</b>		
Ageusia	1	0
Dysgeusia	5	0
Hypogeusia	2	0
Neuralgia	2	0
Restless legs syndrome	1	0
Sensory disturbance	10	0
Sensory loss	1	0
<b>Sleep disturbances NEC</b>		
Poor quality sleep	3	0
Sudden onset of sleep	1	0
<b>Speech and language abnormalities</b>		
Aphonia	1	0
Incoherent	1	0
<b>Spinal cord and nerve root disorders NEC</b>		
Radiculitis brachial	1	0
<b>Tremor (excl congenital)</b>		
Tremor	5	0
<b>Vagus nerve disorders</b>		
Vocal cord paralysis	1	0
<b>Nervous system disorders SOC TOTAL</b>	<b>380</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: Pandemrix

Report Run Date: 01-Dec-2014  
Earliest Reaction Date: 07-Nov-2008

Data Lock Date: 28-Nov-2014 19:00:07  
MedDRA Version: MedDRA 17.1

Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i><b>Abortions spontaneous</b></i>		
Abortion spontaneous	4	0
Abortion spontaneous complete	1	0
<i><b>Foetal complications NEC</b></i>		
Foetal hypokinesia	1	0
Hydrops foetalis	1	0
<i><b>Gestational age and weight conditions</b></i>		
Premature baby	2	0
<i><b>Haemorrhagic complications of pregnancy</b></i>		
Haemorrhage in pregnancy	2	0
<i><b>Labour onset and length abnormalities</b></i>		
Induced labour	1	0
<i><b>Normal pregnancy, labour and delivery</b></i>		
Pregnancy	1	0
Uterine contractions during pregnancy	2	0
<i><b>Placental abnormalities (excl neoplasms)</b></i>		
Placental disorder	1	0
<i><b>Stillbirth and foetal death</b></i>		
Stillbirth	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>17</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: Pandemrix

Report Run Date: 01-Dec-2014  
Earliest Reaction Date: 07-Nov-2008

Data Lock Date: 28-Nov-2014 19:00:07  
MedDRA Version: MedDRA 17.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<i>Anxiety symptoms</i>		
Anxiety	3	0
Nervousness	2	0
<i>Confusion and disorientation</i>		
Confusional state	1	0
<i>Depressive disorders</i>		
Depression	4	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	8	0
<i>Eating disorders NEC</i>		
Food aversion	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	1	0
Irritability	4	0
<i>Increased physical activity levels</i>		
Restlessness	4	0
<i>Learning disorders</i>		
Reading disorder	1	0
<i>Mental disorders NEC</i>		
Mental disorder	1	0
<i>Mood alterations with depressive symptoms</i>		
Depressive symptom	2	0
<i>Narcolepsy and associated conditions</i>		
Sleep attacks	1	0
<i>Parasomnias</i>		
Abnormal dreams	1	0
<i>Perception disturbances</i>		
Hallucination	2	0
<i>Psychotic disorder NEC</i>		
Psychotic disorder	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	3	0
<i>Somatoform disorders</i>		
Psychogenic seizure	1	0
<i>Suicidal and self-injurious behaviour</i>		
Suicidal ideation	1	0
Suicide attempt	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>43</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: Pandemrix

Report Run Date: 01-Dec-2014  
Earliest Reaction Date: 07-Nov-2008

Data Lock Date: 28-Nov-2014 19:00:07  
MedDRA Version: MedDRA 17.1

Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i><b>Bladder and urethral symptoms</b></i>		
Incontinence	1	0
Micturition urgency	1	0
Urinary incontinence	2	0
Urinary retention	1	0
<i><b>Glomerulonephritis and nephrotic syndrome</b></i>		
Glomerulonephritis acute	1	0
IgA nephropathy	1	0
<i><b>Nephropathies and tubular disorders NEC</b></i>		
Nephropathy	1	0
<i><b>Renal failure and impairment</b></i>		
Renal impairment	1	0
<i><b>Urinary abnormalities</b></i>		
Proteinuria	1	0
<i><b>Urinary tract signs and symptoms NEC</b></i>		
Polyuria	1	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>11</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: Pandemrix

Report Run Date: 01-Dec-2014  
Earliest Reaction Date: 07-Nov-2008

Data Lock Date: 28-Nov-2014 19:00:07  
MedDRA Version: MedDRA 17.1

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Breast signs and symptoms</b></i>		
Breast pain	1	0
Breast tenderness	2	0
<i><b>Menstruation with decreased bleeding</b></i>		
Amenorrhoea	1	0
<i><b>Menstruation with increased bleeding</b></i>		
Menorrhagia	1	0
<i><b>Reproductive tract signs and symptoms NEC</b></i>		
Genital burning sensation	1	0
Pelvic pain	2	0
<i><b>Testicular and epididymal disorders NEC</b></i>		
Testicular swelling	1	0
<i><b>Vulvovaginal disorders NEC</b></i>		
Vaginal haemorrhage	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>10</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: Pandemrix

Report Run Date: 01-Dec-2014  
Earliest Reaction Date: 07-Nov-2008

Data Lock Date: 28-Nov-2014 19:00:07  
MedDRA Version: MedDRA 17.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i>Breathing abnormalities</i>		
Dyspnoea	23	0
Hyperventilation	1	0
Respiratory distress	3	0
<i>Bronchospasm and obstruction</i>		
Asthma	5	0
Chronic obstructive pulmonary disease	2	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Cough	20	0
Productive cough	3	0
<i>Lower respiratory tract signs and symptoms</i>		
Increased bronchial secretion	1	0
Rhonchi	2	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	2	0
<i>Nasal disorders NEC</i>		
Epistaxis	5	0
<i>Neonatal hypoxic conditions</i>		
Neonatal asphyxia	1	0
<i>Parenchymal lung disorders NEC</i>		
Interstitial lung disease	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	1	0
Pharyngeal hypoaesthesia	1	0
Pharyngeal oedema	1	0
<i>Respiratory failures (excl neonatal)</i>		
Respiratory failure	3	1
<i>Respiratory signs and symptoms NEC</i>		
Respiration abnormal	2	0
Suffocation feeling	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Dry throat	1	0
Dysphonia	1	0
Increased upper airway secretion	1	0
Oropharyngeal discomfort	1	0
Oropharyngeal pain	8	0
Rhinorrhoea	3	0
Sneezing	1	0
Throat irritation	2	0
Throat tightness	4	0
<b>Respiratory disorders SOC TOTAL</b>	<b>101</b>	<b>1</b>



# Case Series Drug Analysis Print

Name: Pandemrix

Report Run Date: 01-Dec-2014  
Earliest Reaction Date: 07-Nov-2008

Data Lock Date: 28-Nov-2014 19:00:07  
MedDRA Version: MedDRA 17.1

Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<i><b>Alopecias</b></i>		
Alopecia	2	0
Alopecia totalis	1	0
<i><b>Angioedemas</b></i>		
Swelling face	3	0
<i><b>Apocrine and eccrine gland disorders</b></i>		
Cold sweat	5	0
Hyperhidrosis	15	0
Night sweats	2	0
<i><b>Bullous conditions</b></i>		
Blister	3	0
Erythema multiforme	1	0
<i><b>Dermal and epidermal conditions NEC</b></i>		
Dry skin	1	0
Pain of skin	5	0
Papule	2	0
Skin disorder	1	0
Skin swelling	1	0
Skin warm	1	0
<i><b>Dermatitis and eczema</b></i>		
Eczema	2	0
<i><b>Erythemas</b></i>		
Erythema	30	0
Palmar erythema	1	0
Rash erythematous	1	0
<i><b>Exfoliative conditions</b></i>		
Skin exfoliation	2	0
<i><b>Nail and nail bed conditions (excl infections and infestations)</b></i>		
Nail disorder	1	0
<i><b>Papulosquamous conditions</b></i>		
Parapsoriasis	1	0
Pityriasis lichenoides et varioliformis acuta	1	0
Rash papular	1	0
<i><b>Pruritus NEC</b></i>		
Pruritus	22	0
Pruritus generalised	4	0
Rash pruritic	8	0
<i><b>Purpura and related conditions</b></i>		
Ecchymosis	1	0
Petechiae	1	0
<i><b>Rashes, eruptions and exanthems NEC</b></i>		
Rash	18	0
Rash generalised	4	0
Rash macular	1	0
<i><b>Skin and subcutaneous tissue ulcerations</b></i>		
Skin ulcer	1	0
<i><b>Urticarias</b></i>		
Urticaria	38	0
<b>Skin disorders SOC TOTAL</b>	<b>181</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: Pandemrix

Report Run Date: 01-Dec-2014  
Earliest Reaction Date: 07-Nov-2008

Data Lock Date: 28-Nov-2014 19:00:07  
MedDRA Version: MedDRA 17.1

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

# Case Series Drug Analysis Print

Name: Pandemrix

Report Run Date: 01-Dec-2014

Data Lock Date: 28-Nov-2014 19:00:07

Earliest Reaction Date: 07-Nov-2008

MedDRA Version: MedDRA 17.1

Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Joint therapeutic procedures</i>		
Wrist surgery	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>1</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: Pandemrix

Report Run Date: 01-Dec-2014  
Earliest Reaction Date: 07-Nov-2008

Data Lock Date: 28-Nov-2014 19:00:07  
MedDRA Version: MedDRA 17.1

Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i>Haemorrhages NEC</i>		
Haematoma	1	0
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	1	0
<i>Peripheral vascular disorders NEC</i>		
Flushing	7	0
Hot flush	9	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Raynaud's phenomenon	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	5	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	2	0
<i>Vascular hypotensive disorders</i>		
Hypotension	4	0
<i>Vasculitides NEC</i>		
Vasculitis	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>31</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>2208</b>	<b>8</b>
<b>TOTAL REPORTS</b>	<b>667</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>8</b>