

Case Series Drug Analysis Print

Name: Flucelvax Tetra vaccine reports

Report Run Date: 24-Jan-2022

Data Lock Date: 23-Jan-2022 18:30:04

Earliest Reaction Date: 14-Oct-2018

MedDRA Version: MedDRA 24.1

All UK spontaneous Flucelvax Tetra reports up to including 23/01/2022.

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Reaction Name	Total	Fatal
Blood disorders		
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	2	0
Lymphadenitis	1	0
Lymphadenopathy	22	0
Blood disorders SOC TOTAL	25	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	10	0
<i>Noninfectious myocarditis</i>		
Myocarditis	1	0
<i>Rate and rhythm disorders NEC</i>		
Cardiac flutter	2	0
Tachycardia	3	0
Cardiac disorders SOC TOTAL	16	0

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Ocular disorders congenital NEC</i>		
Colour blindness	1	0
Congenital disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear discomfort	1	0
Ear pain	4	0
<i>Hearing losses</i>		
Deafness neurosensory	1	0
Hypoacusis	2	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	3	0
Vertigo	6	0
Ear disorders SOC TOTAL	17	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Eyelid movement disorders</i>		
Blepharospasm	1	0
<i>Lacrimation disorders</i>		
Dry eye	1	0
Lacrimation increased	1	0
<i>Ocular disorders NEC</i>		
Eye oedema	1	0
Eye pain	2	0
Eye swelling	5	0
Eyelids pruritus	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye irritation	1	0
Eye pruritus	2	0
<i>Ocular sensation disorders</i>		
Photophobia	1	0
<i>Visual disorders NEC</i>		
Vision blurred	4	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness transient	1	0
Visual impairment	2	0
Eye disorders SOC TOTAL	23	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Dental pain and sensation disorders</i>		
Toothache	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	37	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	1	0
Eructation	1	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	2	0
Flatulence	2	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	3	0
Abdominal pain upper	9	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	3	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	60	0
Vomiting	33	0
Vomiting projectile	1	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	2	0
<i>Oral soft tissue disorders NEC</i>		
Uvulitis	1	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	1	0
Oral discomfort	1	0
Oral mucosal eruption	1	0
Oral pruritus	1	0
Paraesthesia oral	7	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	2	0
Mouth swelling	1	0
<i>Stomatitis and ulceration</i>		
Mouth ulceration	1	0
<i>Tongue signs and symptoms</i>		
Glossodynia	1	0
Swollen tongue	3	0
Tongue discolouration	1	0
Tongue eruption	1	0
Gastrointestinal disorders SOC TOTAL	179	0

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site injury	1	0
Administration site joint movement impairment	2	0
Administration site pain	3	0
Administration site swelling	2	0
<i>Application and instillation site reactions</i>		
Application site erythema	1	0
Application site inflammation	1	0
Application site pain	3	0
Application site pruritus	1	0
Application site rash	1	0
Application site swelling	1	0
<i>Asthenic conditions</i>		
Asthenia	13	0
Fatigue	64	0
Malaise	28	0
<i>Death and sudden death</i>		
Death	1	1
<i>Febrile disorders</i>		
Pyrexia	35	0
<i>Feelings and sensations NEC</i>		
Chills	39	0
Feeling abnormal	12	0
Feeling cold	3	0
Feeling hot	16	0
Feeling of body temperature change	4	0
Thirst	2	0
<i>Gait disturbances</i>		
Gait disturbance	1	0
Gait inability	2	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	4	0
Illness	8	0
Influenza like illness	12	0
Irritability postvaccinal	1	0
Peripheral swelling	20	0
Swelling	11	0
Swelling face	5	0
<i>Inflammations</i>		
Inflammation	5	0
Systemic inflammatory response syndrome	1	0
<i>Injection site reactions</i>		
Injected limb mobility decreased	4	0
Injection site bruising	1	0
Injection site discomfort	2	0
Injection site erythema	5	0
Injection site extravasation	1	0
Injection site hypertrophy	1	0
Injection site indentation	1	0
Injection site inflammation	3	0
Injection site mass	1	0
Injection site pain	9	0
Injection site pruritus	4	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site rash	1	0
Injection site reaction	1	0
Injection site swelling	2	0
Oedema NEC		
Oedema peripheral	1	0
Pain and discomfort NEC		
Axillary pain	8	0
Chest discomfort	8	0
Chest pain	1	0
Discomfort	2	0
Facial pain	2	0
Pain	28	0
Tenderness	4	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	74	0
Vaccination failure	1	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	2	0
Shoulder injury related to vaccine administration	7	0
Vaccination site bruising	2	0
Vaccination site discolouration	1	0
Vaccination site discomfort	2	0
Vaccination site erythema	17	0
Vaccination site haemorrhage	2	0
Vaccination site induration	2	0
Vaccination site inflammation	4	0
Vaccination site joint erythema	1	0
Vaccination site joint movement impairment	4	0
Vaccination site joint pain	1	0
Vaccination site mass	2	0
Vaccination site movement impairment	9	0
Vaccination site pain	36	0
Vaccination site pruritus	3	0
Vaccination site rash	8	0
Vaccination site reaction	1	0
Vaccination site swelling	23	0
Vaccination site urticaria	1	0
Vaccination site vesicles	1	0
Vaccination site warmth	7	0
General disorders SOC TOTAL	604	1

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Cholestasis and jaundice</i>		
Jaundice	1	0
Hepatic disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	15	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	15	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	1	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	2	0
Immune-mediated adverse reaction	1	0
Immune system disorders SOC TOTAL	35	0

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Reaction Name	Total	Fatal
Infections		
<i>Bacterial infections NEC</i>		
Administration site cellulitis	1	0
Cellulitis	3	0
Vaccination site cellulitis	1	0
<i>Bone and joint infections</i>		
Vaccination site joint infection	1	0
<i>Coronavirus infections</i>		
COVID-19	1	0
Post-acute COVID-19 syndrome	1	0
<i>Infections NEC</i>		
Injection site abscess	1	0
Vaccination site infection	1	0
<i>Influenza viral infections</i>		
Influenza	9	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	1	0
Pneumonia	2	0
<i>Streptococcal infections</i>		
Pneumonia pneumococcal	1	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	3	0
Pharyngitis	2	0
Rhinitis	1	0
Tonsillitis	1	0
Upper respiratory tract infection	1	0
<i>Viral infections NEC</i>		
Gastroenteritis viral	1	0
Vestibular neuronitis	1	0
Infections SOC TOTAL	33	0

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Reaction Name	Total	Fatal
Injuries		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Maternal exposure during pregnancy	3	0
<i>Gastrointestinal and hepatobiliary procedural complications</i>		
Procedural vomiting	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	3	0
Wrong technique in product usage process	2	0
<i>Muscle, tendon and ligament injuries</i>		
Ligament sprain	1	0
Muscle injury	1	0
<i>Non-site specific injuries NEC</i>		
Fall	1	0
<i>Off label uses</i>		
Off label use	2	0
<i>Product administration errors and issues</i>		
Extra dose administered	1	0
Incorrect route of product administration	1	0
Poor quality product administered	1	0
Product administered at inappropriate site	5	0
Product administration error	1	0
Wrong product administered	1	0
<i>Skin injuries NEC</i>		
Contusion	6	0
<i>Spinal cord injuries NEC</i>		
Central cord syndrome	1	0
Injuries SOC TOTAL	31	0

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Reaction Name	Total	Fatal
Investigations		
<i>Autoimmunity analyses</i>		
Anti-HLA antibody test positive	1	0
<i>Blood gas and acid base analyses</i>		
Oxygen saturation decreased	2	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose decreased	1	0
Blood glucose increased	1	0
<i>ECG investigations</i>		
Electrocardiogram abnormal	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate increased	5	0
Heart rate irregular	2	0
<i>Liver function analyses</i>		
Alanine aminotransferase increased	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature fluctuation	2	0
Body temperature increased	1	0
Palpatory finding abnormal	1	0
Weight increased	2	0
<i>Reproductive hormone analyses</i>		
Blood testosterone decreased	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure increased	1	0
Investigations SOC TOTAL	22	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	16	0
<i>Fat soluble vitamin deficiencies and disorders</i>		
Vitamin D deficiency	1	0
<i>Metabolic disorders NEC</i>		
Hypermetabolism	1	0
Metabolic disorders SOC TOTAL	18	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	3	0
<i>Bone related signs and symptoms</i>		
Pain in jaw	1	0
<i>Bursal disorders</i>		
Bursitis	1	0
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	2	0
<i>Joint related disorders NEC</i>		
Periarthritis	3	0
Rotator cuff syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	50	0
Joint stiffness	2	0
Joint swelling	2	0
<i>Muscle infections and inflammations</i>		
Myositis	1	0
<i>Muscle pains</i>		
Fibromyalgia	1	0
Myalgia	41	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle fatigue	3	0
Muscle spasms	4	0
Muscle tightness	1	0
Muscle twitching	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	7	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Mobility decreased	3	0
Musculoskeletal stiffness	14	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	8	0
Limb discomfort	5	0
Musculoskeletal discomfort	1	0
Neck pain	7	0
Pain in extremity	51	0
<i>Soft tissue disorders NEC</i>		
Neck mass	1	0
<i>Tendon disorders</i>		
Tendonitis	2	0
Muscle & tissue disorders SOC TOTAL	216	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Absence seizures		
Petit mal epilepsy	2	0
Acute polyneuropathies		
Guillain-Barre syndrome	4	0
Central nervous system aneurysms and dissections		
Intracranial aneurysm	1	0
Central nervous system haemorrhages and cerebrovascular accidents		
Cerebrovascular accident	1	1
Chronic polyneuropathies		
Acrodynia	1	0
Coordination and balance disturbances		
Nystagmus	1	0
Cortical dysfunction NEC		
Aphasia	1	0
Disturbances in consciousness NEC		
Lethargy	2	0
Loss of consciousness	2	0
Somnolence	2	0
Syncope	19	0
Dyskinesias and movement disorders NEC		
Dyskinesia	1	0
Hypokinesia	3	0
Facial cranial nerve disorders		
Bell's palsy	1	0
Headaches NEC		
Headache	69	0
Tension headache	2	0
Mental impairment (excl dementia and memory loss)		
Disturbance in attention	3	0
Migraine headaches		
Migraine	9	0
Migraine with aura	1	0
Myelitis (incl infective)		
Myelitis transverse	1	0
Narcolepsy and hypersomnia		
Hypersomnia	2	0
Nervous system disorders NEC		
Nervous system disorder	1	0
Neurological signs and symptoms NEC		
Dizziness	49	0
Dizziness postural	1	0
Head discomfort	1	0
Neurological symptom	1	0
Presyncope	6	0
Unresponsive to stimuli	2	0
Paraesthesias and dysaesthesias		
Burning sensation	4	0
Hyperaesthesia	2	0
Hypoaesthesia	17	0
Paraesthesia	26	0
Peripheral neuropathies NEC		
Neuralgic amyotrophy	2	0
Seizures and seizure disorders NEC		

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Epilepsy	2	0
Seizure	4	0
<i>Sensory abnormalities NEC</i>		
Ageusia	3	0
Dysgeusia	3	0
Electric shock sensation	1	0
Hypogeusia	1	0
Neuralgia	4	0
Sensory disturbance	2	0
Sensory loss	2	0
Taste disorder	1	0
<i>Spinal cord and nerve root disorders NEC</i>		
Radiculitis brachial	1	0
<i>Tremor (excl congenital)</i>		
Tremor	6	0
Nervous system disorders SOC TOTAL	270	1

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Reaction Name	Total	Fatal
<i>Device physical property and chemical issues</i>		
Needle issue	1	0
Syringe issue	1	0
null SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Anxiety symptoms</i>		
Anxiety	2	0
Tension	1	0
<i>Confusion and disorientation</i>		
Confusional state	2	0
Disorientation	1	0
<i>Depressive disorders</i>		
Depression	1	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	1	0
Dissociation	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	6	0
<i>Eating disorders NEC</i>		
Eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Irritability	5	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	1	0
<i>Mood disorders NEC</i>		
Apathy	1	0
<i>Panic attacks and disorders</i>		
Panic attack	1	0
<i>Parasomnias</i>		
Abnormal dreams	2	0
Rapid eye movements sleep abnormal	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	3	0
<i>Thinking disturbances</i>		
Thinking abnormal	1	0
<i>Tic disorders</i>		
Tic	1	0
Psychiatric disorders SOC TOTAL	32	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	1	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	1	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Pelvic pain	1	0
Reproductive & breast disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	12	0
Respiration abnormal	2	0
Tachypnoea	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	2	0
Chronic obstructive pulmonary disease	1	0
Wheezing	2	0
<i>Coughing and associated symptoms</i>		
Cough	9	0
Productive cough	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	3	0
<i>Nasal disorders NEC</i>		
Epistaxis	1	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinus congestion	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal paraesthesia	2	0
Pharyngeal swelling	1	0
Pharyngeal ulceration	1	0
<i>Pulmonary oedemas</i>		
Pulmonary congestion	1	0
<i>Respiratory failures (excl neonatal)</i>		
Respiratory failure	1	1
<i>Respiratory tract disorders NEC</i>		
Respiratory tract inflammation	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	2	0
Dry throat	1	0
Oropharyngeal discomfort	1	0
Oropharyngeal pain	15	0
Paranasal sinus discomfort	1	0
Rhinorrhoea	6	0
Sinus pain	2	0
Sneezing	4	0
Throat irritation	2	0
Throat tightness	1	0
Respiratory disorders SOC TOTAL	77	1

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Reaction Name	Total	Fatal
Skin disorders		
Angioedemas		
Angioedema	2	0
Apocrine and eccrine gland disorders		
Cold sweat	3	0
Hyperhidrosis	8	0
Miliaria	2	0
Night sweats	1	0
Bullous conditions		
Blister	3	0
Dermal and epidermal conditions NEC		
Pain of skin	1	0
Papule	1	0
Scar pain	1	0
Skin burning sensation	1	0
Skin discolouration	1	0
Skin disorder	1	0
Skin induration	2	0
Skin reaction	5	0
Skin swelling	3	0
Skin texture abnormal	2	0
Skin warm	3	0
Skin weeping	1	0
Dermatitis and eczema		
Dermatitis	2	0
Dermatitis allergic	6	0
Eczema	1	0
Neurodermatitis	2	0
Dermatitis ascribed to specific agent		
Drug eruption	1	0
Erythemas		
Erythema	25	0
Exfoliative conditions		
Skin exfoliation	1	0
Papulosquamous conditions		
Lichen planus	1	0
Pityriasis rosea	1	0
Pruritus NEC		
Pruritus	32	0
Psoriatic conditions		
Psoriasis	1	0
Purpura and related conditions		
Petechiae	1	0
Rashes, eruptions and exanthems NEC		
Rash	20	0
Rash erythematous	3	0
Rash macular	3	0
Rash maculo-papular	1	0
Rash papular	4	0
Rash vesicular	1	0
Skin and subcutaneous conditions NEC		
Skin mass	1	0
Skin and subcutaneous tissue ulcerations		
Skin erosion	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Urticarias</i>		
Cold urticaria	1	0
Urticaria	24	0
Skin disorders SOC TOTAL	174	0

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Earliest Reaction Date: 14-Oct-2018

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Bedridden	1	0
Immobile	3	0
Impaired work ability	3	0
Loss of personal independence in daily activities	3	0
Social circumstances SOC TOTAL	10	0

Case Series Drug Analysis Print

Name: Flucelvax vaccine reports

Report Run Date: 24-Jan-2022

Data Lock Date: 23-Jan-2022 18:30:04

Earliest Reaction Date: 14-Oct-2018

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Immunisations</i>		
Immunisation	2	0
<i>Therapeutic procedures NEC</i>		
Interchange of vaccine products	1	0
Surgical & medical procedures SOC TOTAL	3	0

Case Series Drug Analysis Print

Name: Flucelvax vaccine reports

Report Run Date: 24-Jan-2022
Earliest Reaction Date: 14-Oct-2018

Data Lock Date: 23-Jan-2022 18:30:04
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Vascular disorders		
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	1	0
Flushing	2	0
Hot flush	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Jugular vein occlusion	1	0
Peripheral coldness	2	0
Vasoconstriction	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	3	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	2	0
<i>Vascular hypotensive disorders</i>		
Hypotension	4	0
Vascular disorders SOC TOTAL	18	0
TOTAL REACTIONS FOR DRUG	1811	3
TOTAL REPORTS	678	
TOTAL FATAL OUTCOME REPORTS		3