Supplementary Material

Disease-modifying therapies (DMTs) in pregnant and lactating women with multiple sclerosis: analysis of real-world data from EudraVigilance database

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1 Supplementary Tables

Table S1. Preferred Terms reported with alemtuzumab, glatiramer, natalizumab, and ocrelizumab in Individual Case Safety Reports related to pregnancy and neonatal topics of the Eudravigilance database.

Part I – Mother other ADRs

Mother other ADR	ALEMTUZUMAB (N=501)	GLATIRAMER (N=254)	NATALIZUMAB (N=204)	OCRELIZUMAB (N=69)	Overall (N=1,028)
Abdominal discomfort	1 (0.2%)	1 (0.4%)	0 (0%)	0 (0%)	2 (0.2%)
Abdominal distension	1 (0.2%)	1 (0.4%)	0 (0%)	0 (0%)	2 (0.2%)
Abdominal pain upper	2 (0.4%)	0 (0%)	0 (0%)	1 (1.4%)	3 (0.3%)
Acne	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Alanine aminotransferase increased	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Alopecia	2 (0.4%)	1 (0.4%)	0 (0%)	0 (0%)	3 (0.3%)

Anaemia	2 (0.4%)	4 (1.6%)	7 (3.4%)	0 (0%)	13 (1.3%)
Anti-thyroid antibody positive	6 (1.2%)	0 (0%)	0 (0%)	0 (0%)	6 (0.6%)
Anxiety	4 (0.8%)	1 (0.4%)	0 (0%)	0 (0%)	5 (0.5%)
Aphasia	2 (0.4%)	0 (0%)	0 (0%)	0 (0%)	2 (0.2%)
Arthralgia	2 (0.4%)	3 (1.2%)	0 (0%)	0 (0%)	5 (0.5%)
Asthenia	3 (0.6%)	2 (0.8%)	1 (0.5%)	0 (0%)	6 (0.6%)
Autoimmune myocarditis	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Autoimmune thyroiditis	3 (0.6%)	0 (0%)	0 (0%)	0 (0%)	3 (0.3%)
Back pain	2 (0.4%)	3 (1.2%)	1 (0.5%)	0 (0%)	6 (0.6%)
Bacterial test	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Bacterial test positive	2 (0.4%)	0 (0%)	0 (0%)	0 (0%)	2 (0.2%)
Band neutrophil count increased	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Band neutrophil percentage increased	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Band sensation	3 (0.6%)	0 (0%)	0 (0%)	0 (0%)	3 (0.3%)
Basal ganglia haemorrhage	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Basedow's disease	10 (2.0%)	0 (0%)	0 (0%)	0 (0%)	10 (1.0%)
Blister	3 (0.6%)	0 (0%)	0 (0%)	0 (0%)	3 (0.3%)
Blood creatinine decreased	3 (0.6%)	0 (0%)	0 (0%)	0 (0%)	3 (0.3%)
Blood creatinine increased	3 (0.6%)	1 (0.4%)	0 (0%)	0 (0%)	4 (0.4%)
Blood disorder	1 (0.2%)	0 (0%)	1 (0.5%)	0 (0%)	2 (0.2%)
Blood iron decreased	1 (0.2%)	1 (0.4%)	0 (0%)	0 (0%)	2 (0.2%)
Blood ketone body increased	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Blood pressure fluctuation	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Blood pressure increased	1 (0.2%)	0 (0%)	1 (0.5%)	0 (0%)	2 (0.2%)
Blood sodium decreased	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Blood thyroid stimulating hormone abnormal	2 (0.4%)	0 (0%)	0 (0%)	0 (0%)	2 (0.2%)
Blood thyroid stimulating hormone decreased	3 (0.6%)	0 (0%)	0 (0%)	0 (0%)	3 (0.3%)
Blood thyroid stimulating hormone increased	4 (0.8%)	0 (0%)	0 (0%)	0 (0%)	4 (0.4%)
Blood urine present	3 (0.6%)	0 (0%)	0 (0%)	0 (0%)	3 (0.3%)
Body temperature increased	3 (0.6%)	1 (0.4%)	0 (0%)	0 (0%)	4 (0.4%)
Bradycardia	5 (1.0%)	0 (0%)	1 (0.5%)	0 (0%)	6 (0.6%)
Bronchiolitis	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)

Bruxism	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
C-reactive protein increased	3 (0.6%)	0 (0%)	1 (0.5%)	0 (0%)	4 (0.4%)
Cells in urine	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Cerebrovascular accident	1 (0.2%)	0 (0%)	1 (0.5%)	0 (0%)	2 (0.2%)
Chest discomfort	1 (0.2%)	1 (0.4%)	0 (0%)	0 (0%)	2 (0.2%)
Chest pain	5 (1.0%)	1 (0.4%)	0 (0%)	0 (0%)	6 (0.6%)
Chromaturia	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Cognitive disorder	2 (0.4%)	0 (0%)	0 (0%)	0 (0%)	2 (0.2%)
Constipation	4 (0.8%)	1 (0.4%)	0 (0%)	1 (1.4%)	6 (0.6%)
Contusion	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Coordination abnormal	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Cough	3 (0.6%)	2 (0.8%)	0 (0%)	1 (1.4%)	6 (0.6%)
Creatinine urine decreased	3 (0.6%)	0 (0%)	0 (0%)	0 (0%)	3 (0.3%)
Crystal urine present	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Culture urine positive	5 (1.0%)	0 (0%)	0 (0%)	0 (0%)	5 (0.5%)
Cytomegalovirus infection	1 (0.2%)	0 (0%)	1 (0.5%)	0 (0%)	2 (0.2%)
Death	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Decreased appetite	1 (0.2%)	1 (0.4%)	0 (0%)	0 (0%)	2 (0.2%)
Depression	3 (0.6%)	1 (0.4%)	1 (0.5%)	1 (1.4%)	6 (0.6%)
Diarrhoea	6 (1.2%)	1 (0.4%)	0 (0%)	1 (1.4%)	8 (0.8%)
Disorientation	2 (0.4%)	0 (0%)	0 (0%)	0 (0%)	2 (0.2%)
Dizziness	5 (1.0%)	0 (0%)	0 (0%)	0 (0%)	5 (0.5%)
Drug ineffective	3 (0.6%)	0 (0%)	1 (0.5%)	0 (0%)	4 (0.4%)
Dry skin	2 (0.4%)	0 (0%)	0 (0%)	0 (0%)	2 (0.2%)
Dysarthria	1 (0.2%)	0 (0%)	1 (0.5%)	0 (0%)	2 (0.2%)
Dysgeusia	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Dyspepsia	1 (0.2%)	1 (0.4%)	0 (0%)	0 (0%)	2 (0.2%)
Dysphonia	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Dyspnoea	7 (1.4%)	4 (1.6%)	1 (0.5%)	1 (1.4%)	13 (1.3%)
Electric shock sensation	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Encephalitis autoimmune	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Enterovirus infection	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)

Eosinophil count increased	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Epistaxis	4 (0.8%)	0 (0%)	0 (0%)	0 (0%)	4 (0.4%)
Erythema	1 (0.2%)	1 (0.4%)	0 (0%)	1 (1.4%)	3 (0.3%)
Erythema migrans	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Exophthalmos	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Extrasystoles	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Eye contusion	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Eye disorder	1 (0.2%)	0 (0%)	1 (0.5%)	0 (0%)	2 (0.2%)
Fatigue	10 (2.0%)	2 (0.8%)	1 (0.5%)	0 (0%)	13 (1.3%)
Feeding disorder	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Feeling abnormal	3 (0.6%)	2 (0.8%)	0 (0%)	0 (0%)	5 (0.5%)
Feeling hot	3 (0.6%)	0 (0%)	0 (0%)	0 (0%)	3 (0.3%)
Flatulence	1 (0.2%)	1 (0.4%)	0 (0%)	0 (0%)	2 (0.2%)
Flushing	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Gait disturbance	1 (0.2%)	1 (0.4%)	1 (0.5%)	0 (0%)	3 (0.3%)
Gastrointestinal sounds abnormal	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Gastrooesophageal reflux disease	4 (0.8%)	0 (0%)	1 (0.5%)	0 (0%)	5 (0.5%)
Generalised tonic-clonic seizure	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Gingival bleeding	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Goitre	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Haematocrit decreased	3 (0.6%)	0 (0%)	2 (1.0%)	0 (0%)	5 (0.5%)
Haematoma	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Haemoglobin decreased	3 (0.6%)	0 (0%)	3 (1.5%)	0 (0%)	6 (0.6%)
Haemorrhage	2 (0.4%)	2 (0.8%)	8 (3.9%)	3 (4.3%)	15 (1.5%)
Hair texture abnormal	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Headache	6 (1.2%)	3 (1.2%)	0 (0%)	1 (1.4%)	10 (1.0%)
Heart rate increased	5 (1.0%)	0 (0%)	0 (0%)	0 (0%)	5 (0.5%)
Heavy menstrual bleeding	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Hemiparaesthesia	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Hemiparesis	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Herpes zoster	1 (0.2%)	0 (0%)	0 (0%)	1 (1.4%)	2 (0.2%)
Hot flush	4 (0.8%)	0 (0%)	0 (0%)	0 (0%)	4 (0.4%)

Hyperhidrosis	4 (0.8%)	0 (0%)	0 (0%)	0 (0%)	4 (0.4%)
Hypertension	1 (0.2%)	0 (0%)	4 (2.0%)	0 (0%)	5 (0.5%)
Hyperthyroidism	9 (1.8%)	0 (0%)	0 (0%)	0 (0%)	9 (0.9%)
Hypertonia	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Hypoaesthesia	3 (0.6%)	7 (2.8%)	0 (0%)	0 (0%)	10 (1.0%)
Hypohidrosis	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Hypothyroidism	5 (1.0%)	0 (0%)	0 (0%)	0 (0%)	5 (0.5%)
Immune reconstitution inflammatory syndrome	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Immune thrombocytopenia	5 (1.0%)	0 (0%)	0 (0%)	0 (0%)	5 (0.5%)
Increased appetite	3 (0.6%)	0 (0%)	0 (0%)	0 (0%)	3 (0.3%)
Infection	1 (0.2%)	1 (0.4%)	2 (1.0%)	0 (0%)	4 (0.4%)
Influenza	1 (0.2%)	0 (0%)	2 (1.0%)	0 (0%)	3 (0.3%)
Infusion site bruising	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Infusion site induration	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Initial insomnia	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Insomnia	4 (0.8%)	0 (0%)	0 (0%)	0 (0%)	4 (0.4%)
Irritability	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Klebsiella test positive	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Lethargy	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Leukaemia	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Loss of consciousness	2 (0.4%)	0 (0%)	0 (0%)	0 (0%)	2 (0.2%)
Lower respiratory tract infection	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Lymphadenectomy	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Lymphadenitis	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Lymphocyte count decreased	9 (1.8%)	1 (0.4%)	0 (0%)	1 (1.4%)	11 (1.1%)
Lymphocyte percentage decreased	2 (0.4%)	0 (0%)	0 (0%)	0 (0%)	2 (0.2%)
Lymphoid tissue hyperplasia	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Lymphopenia	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Malaise	4 (0.8%)	2 (0.8%)	0 (0%)	0 (0%)	6 (0.6%)
Mean cell haemoglobin concentration increased	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)

Mean cell haemoglobin increased	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Mean cell volume increased	1 (0.2%)	0 (0%)	1 (0.5%)	0 (0%)	2 (0.2%)
Memory impairment	1 (0.2%)	1 (0.4%)	1 (0.5%)	0 (0%)	3 (0.3%)
Menstrual disorder	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Menstruation delayed	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Menstruation irregular	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Monocyte count decreased	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Monocyte count increased	3 (0.6%)	0 (0%)	0 (0%)	0 (0%)	3 (0.3%)
Monocyte percentage increased	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Mood altered	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Motor dysfunction	1 (0.2%)	1 (0.4%)	0 (0%)	0 (0%)	2 (0.2%)
Multiple sclerosis relapse	5 (1.0%)	30 (11.8%)	28 (13.7%)	5 (7.2%)	68 (6.6%)
Muscle spasms	1 (0.2%)	0 (0%)	1 (0.5%)	0 (0%)	2 (0.2%)
Muscle tightness	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Muscular weakness	3 (0.6%)	1 (0.4%)	0 (0%)	0 (0%)	4 (0.4%)
Musculoskeletal disorder	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Musculoskeletal stiffness	2 (0.4%)	2 (0.8%)	0 (0%)	0 (0%)	4 (0.4%)
Myalgia	5 (1.0%)	0 (0%)	0 (0%)	0 (0%)	5 (0.5%)
Myasthenia gravis	2 (0.4%)	0 (0%)	0 (0%)	0 (0%)	2 (0.2%)
Myxoedema	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Nasal congestion	3 (0.6%)	0 (0%)	0 (0%)	0 (0%)	3 (0.3%)
Nasal injury	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Nasopharyngitis	1 (0.2%)	1 (0.4%)	0 (0%)	0 (0%)	2 (0.2%)
Nausea	8 (1.6%)	0 (0%)	2 (1.0%)	0 (0%)	10 (1.0%)
Nervous system disorder	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Neurodermatitis	1 (0.2%)	1 (0.4%)	0 (0%)	0 (0%)	2 (0.2%)
Neutropenia	1 (0.2%)	0 (0%)	0 (0%)	1 (1.4%)	2 (0.2%)
Neutrophil count decreased	1 (0.2%)	0 (0%)	1 (0.5%)	0 (0%)	2 (0.2%)
Neutrophil count increased	4 (0.8%)	0 (0%)	0 (0%)	0 (0%)	4 (0.4%)
Neutrophil percentage increased	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Nitrite urine present	2 (0.4%)	0 (0%)	0 (0%)	0 (0%)	2 (0.2%)
Nocturia	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)

Oedema peripheral	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Optic atrophy	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Oral candidiasis	1 (0.2%)	0 (0%)	0 (0%)	1 (1.4%)	2 (0.2%)
Oropharyngeal pain	4 (0.8%)	0 (0%)	0 (0%)	0 (0%)	4 (0.4%)
Pain	2 (0.4%)	1 (0.4%)	1 (0.5%)	1 (1.4%)	5 (0.5%)
Pain in jaw	3 (0.6%)	0 (0%)	0 (0%)	0 (0%)	3 (0.3%)
Panic attack	3 (0.6%)	0 (0%)	0 (0%)	0 (0%)	3 (0.3%)
Peripheral swelling	1 (0.2%)	1 (0.4%)	0 (0%)	1 (1.4%)	3 (0.3%)
Petechiae	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
pH urine increased	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Pharyngitis	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Platelet count decreased	3 (0.6%)	0 (0%)	1 (0.5%)	0 (0%)	4 (0.4%)
Pollakiuria	2 (0.4%)	0 (0%)	0 (0%)	0 (0%)	2 (0.2%)
Polyarteritis nodosa	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Procalcitonin increased	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Protein total increased	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Pruritus	2 (0.4%)	2 (0.8%)	0 (0%)	1 (1.4%)	5 (0.5%)
Pulmonary hypertension	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Pyrexia	4 (0.8%)	1 (0.4%)	2 (1.0%)	0 (0%)	7 (0.7%)
Rash	4 (0.8%)	0 (0%)	1 (0.5%)	2 (2.9%)	7 (0.7%)
Red blood cell count decreased	3 (0.6%)	0 (0%)	2 (1.0%)	0 (0%)	5 (0.5%)
Red blood cell count increased	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Red blood cells urine positive	3 (0.6%)	0 (0%)	0 (0%)	0 (0%)	3 (0.3%)
Red cell distribution width decreased	2 (0.4%)	0 (0%)	0 (0%)	0 (0%)	2 (0.2%)
Renal pain	2 (0.4%)	0 (0%)	0 (0%)	0 (0%)	2 (0.2%)
Rhinitis	2 (0.4%)	0 (0%)	0 (0%)	0 (0%)	2 (0.2%)
Rosacea	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Salivary gland cancer	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Sensation of foreign body	3 (0.6%)	0 (0%)	0 (0%)	0 (0%)	3 (0.3%)
Sensorimotor disorder	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Sensory disturbance	1 (0.2%)	0 (0%)	0 (0%)	1 (1.4%)	2 (0.2%)
Sinusitis	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)

Skin burning sensation	3 (0.6%)	0 (0%)	0 (0%)	0 (0%)	3 (0.3%)
Skin discolouration	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Skin disorder	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Skin haemorrhage	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Specific gravity urine decreased	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Speech disorder	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Staphylococcal infection	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Status epilepticus	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Stress cardiomyopathy	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Swelling face	1 (0.2%)	1 (0.4%)	0 (0%)	0 (0%)	2 (0.2%)
T-cell type acute leukaemia	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Tachycardia	1 (0.2%)	0 (0%)	2 (1.0%)	0 (0%)	3 (0.3%)
Temperature intolerance	2 (0.4%)	0 (0%)	0 (0%)	0 (0%)	2 (0.2%)
Thrombocytopenia	1 (0.2%)	0 (0%)	4 (2.0%)	0 (0%)	5 (0.5%)
Thyroid cyst	3 (0.6%)	0 (0%)	0 (0%)	0 (0%)	3 (0.3%)
Thyroid disorder	9 (1.8%)	0 (0%)	0 (0%)	0 (0%)	9 (0.9%)
Thyroid function test abnormal	4 (0.8%)	0 (0%)	0 (0%)	0 (0%)	4 (0.4%)
Thyroid stimulating immunoglobulin	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Thyroidectomy	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Thyroxine decreased	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Thyroxine free abnormal	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Thyroxine free decreased	2 (0.4%)	0 (0%)	0 (0%)	0 (0%)	2 (0.2%)
Thyroxine increased	2 (0.4%)	0 (0%)	0 (0%)	0 (0%)	2 (0.2%)
Tongue discolouration	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Transformation to acute myeloid leukaemia	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Tremor	5 (1.0%)	3 (1.2%)	0 (0%)	0 (0%)	8 (0.8%)
Tri-iodothyronine free abnormal	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Tri-iodothyronine increased	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Type 1 diabetes mellitus	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Underweight	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Urinary incontinence	1 (0.2%)	0 (0%)	1 (0.5%)	0 (0%)	2 (0.2%)
Urinary tract infection	2 (0.4%)	0 (0%)	4 (2.0%)	1 (1.4%)	7 (0.7%)

Urinary tract infection staphylococcal	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Urine abnormality	6 (1.2%)	0 (0%)	0 (0%)	0 (0%)	6 (0.6%)
Urine analysis abnormal	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Urine bilirubin decreased	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Urine bilirubin increased	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Urine leukocyte esterase positive	2 (0.4%)	0 (0%)	0 (0%)	0 (0%)	2 (0.2%)
Urticaria	3 (0.6%)	1 (0.4%)	0 (0%)	2 (2.9%)	6 (0.6%)
Vaginal discharge	1 (0.2%)	1 (0.4%)	0 (0%)	0 (0%)	2 (0.2%)
Vasoconstriction	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Vein disorder	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Vision blurred	1 (0.2%)	0 (0%)	0 (0%)	1 (1.4%)	2 (0.2%)
Vomiting	2 (0.4%)	4 (1.6%)	2 (1.0%)	1 (1.4%)	9 (0.9%)
Weight decreased	3 (0.6%)	0 (0%)	2 (1.0%)	2 (2.9%)	7 (0.7%)
Weight increased	2 (0.4%)	0 (0%)	0 (0%)	0 (0%)	2 (0.2%)
White blood cell count decreased	2 (0.4%)	0 (0%)	0 (0%)	0 (0%)	2 (0.2%)
White blood cell count increased	3 (0.6%)	0 (0%)	2 (1.0%)	0 (0%)	5 (0.5%)
White blood cells urine positive	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Abdominal pain	0 (0%)	1 (0.4%)	1 (0.5%)	0 (0%)	2 (0.2%)
Amenorrhoea	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Anaphylactic reaction	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Angioedema	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Areflexia	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Ataxia	0 (0%)	1 (0.4%)	2 (1.0%)	0 (0%)	3 (0.3%)
Bladder hypertrophy	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Blood pressure abnormal	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Breast pain	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Caesarean delivery on maternal request	0 (0%)	4 (1.6%)	0 (0%)	0 (0%)	4 (0.4%)
Cardiac murmur	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Central nervous system lesion	0 (0%)	2 (0.8%)	0 (0%)	0 (0%)	2 (0.2%)
Cervix disorder	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Chills	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Choking	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)

Condition aggravated	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Congenital musculoskeletal disorder of limbs	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Cyst	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Deafness unilateral	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Delivery	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Diabetes insipidus	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Discomfort	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Drug hypersensitivity	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Dysaesthesia	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Dyskinesia	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Expanded disability status scale score increased	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Eye swelling	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Eyelid sensory disorder	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Face oedema	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Fall	0 (0%)	1 (0.4%)	1 (0.5%)	0 (0%)	2 (0.2%)
Formication	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Gait inability	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Gamma-glutamyltransferase increased	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Growth retardation	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Hand deformity	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Heart rate decreased	0 (0%)	1 (0.4%)	0 (0%)	1 (1.4%)	2 (0.2%)
Herpes simplex meningoencephalitis	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Hormone level abnormal	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Hyperglycaemia	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Hyperreflexia	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Hypersensitivity	0 (0%)	4 (1.6%)	0 (0%)	0 (0%)	4 (0.4%)
Hyperthermia	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Hypoaesthesia oral	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Immediate post-injection reaction	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Inadequate analgesia	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Influenza like illness	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)

Infusion related reaction	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Inguinal hernia	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Injection site atrophy	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Injection site discolouration	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Injection site erythema	0 (0%)	9 (3.5%)	0 (0%)	0 (0%)	9 (0.9%)
Injection site haematoma	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Injection site hypoaesthesia	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Injection site induration	0 (0%)	7 (2.8%)	0 (0%)	0 (0%)	7 (0.7%)
Injection site irritation	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Injection site mass	0 (0%)	2 (0.8%)	0 (0%)	0 (0%)	2 (0.2%)
Injection site pain	0 (0%)	6 (2.4%)	0 (0%)	0 (0%)	6 (0.6%)
Injection site pruritus	0 (0%)	5 (2.0%)	0 (0%)	0 (0%)	5 (0.5%)
Injection site swelling	0 (0%)	4 (1.6%)	0 (0%)	0 (0%)	4 (0.4%)
Injection site urticaria	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Interferon gamma release assay positive	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Iron deficiency anaemia	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
JC virus infection	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Lactation disorder	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Lhermitte's sign	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Lip swelling	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Lymphadenopathy	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Lymphocytosis	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Magnetic resonance imaging abnormal	0 (0%)	1 (0.4%)	0 (0%)	1 (1.4%)	2 (0.2%)
Menometrorrhagia	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Movement disorder	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Needle fatigue	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Obesity	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Overweight	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Paraesthesia	0 (0%)	2 (0.8%)	0 (0%)	0 (0%)	2 (0.2%)
Perinatal depression	0 (0%)	1 (0.4%)	1 (0.5%)	0 (0%)	2 (0.2%)
Post procedural discomfort	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Presyncope	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)

Procedural pain	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Progesterone decreased	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Proteinuria	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Salpingectomy	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Self-consciousness	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Sense of oppression	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Sepsis	0 (0%)	1 (0.4%)	2 (1.0%)	0 (0%)	3 (0.3%)
Skin indentation	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Skin reaction	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Skin striae	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Spinal cord disorder	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Stress	0 (0%)	2 (0.8%)	1 (0.5%)	0 (0%)	3 (0.3%)
Suppressed lactation	0 (0%)	3 (1.2%)	0 (0%)	0 (0%)	3 (0.3%)
Supraventricular tachycardia	0 (0%)	2 (0.8%)	0 (0%)	0 (0%)	2 (0.2%)
Swelling	0 (0%)	2 (0.8%)	0 (0%)	0 (0%)	2 (0.2%)
Syncope	0 (0%)	3 (1.2%)	0 (0%)	0 (0%)	3 (0.3%)
Therapeutic product effect incomplete	0 (0%)	1 (0.4%)	1 (0.5%)	0 (0%)	2 (0.2%)
Therapeutic product effect variable	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Throat tightness	0 (0%)	1 (0.4%)	0 (0%)	1 (1.4%)	2 (0.2%)
Umbilical hernia	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Uterine disorder	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Vaginal haemorrhage	0 (0%)	1 (0.4%)	2 (1.0%)	3 (4.3%)	6 (0.6%)
Vertigo positional	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Visual impairment	0 (0%)	2 (0.8%)	0 (0%)	0 (0%)	2 (0.2%)
Wheezing	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
White matter lesion	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.1%)
Arrhythmia	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Autism spectrum disorder	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Autoimmune demyelinating disease	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Autoimmune haemolytic anaemia	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Autoimmune neutropenia	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Autonomic nervous system imbalance	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)

Bacterial sepsis	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Beta haemolytic streptococcal infection	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Blood bilirubin increased	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Cardiogenic shock	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Cervix haematoma uterine	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Cervix haemorrhage uterine	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Coagulopathy	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Coronavirus infection	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
COVID-19	0 (0%)	0 (0%)	2 (1.0%)	2 (2.9%)	4 (0.4%)
Coxsackie myocarditis	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Coxsackie viral infection	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Dehydration	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Depressed level of consciousness	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Diaphragmatic injury	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Drug dependence	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Dysmetria	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Epilepsy	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Escherichia vaginitis	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Female reproductive tract disorder	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Gastritis	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Gastrointestinal disorder	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
General physical health deterioration	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Hepatic enzyme increased	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Human chorionic gonadotropin decreased	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Hydrocephalus	0 (0%)	0 (0%)	2 (1.0%)	0 (0%)	2 (0.2%)
Hydronephrosis	0 (0%)	0 (0%)	2 (1.0%)	1 (1.4%)	3 (0.3%)
Hyperbilirubinaemia	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Hypotonia	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Infertility	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Intention tremor	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Iron deficiency	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Kidney enlargement	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)

Kidney infection	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Leukocytosis	0 (0%)	0 (0%)	2 (1.0%)	0 (0%)	2 (0.2%)
Ligament sprain	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Liver function test increased	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Lymphocyte count increased	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Mastitis	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Mean cell haemoglobin concentration decreased	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Meningitis coxsackie viral	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Meningitis enteroviral	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Mitral valve incompetence	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Myelitis	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Neck pain	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Neoplasm malignant	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Nephrolithiasis	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Nephropathy	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Neurological decompensation	0 (0%)	0 (0%)	3 (1.5%)	0 (0%)	3 (0.3%)
Oedema	0 (0%)	0 (0%)	2 (1.0%)	0 (0%)	2 (0.2%)
Optic neuritis	0 (0%)	0 (0%)	3 (1.5%)	0 (0%)	3 (0.3%)
Paraparesis	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Pelvic deformity	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Platelet count abnormal	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Pleural effusion	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Post procedural haematoma	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Protein total decreased	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Renal cyst	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Renal failure	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Respiratory failure	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Respiratory tract infection viral	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
SARS-CoV-2 test positive	0 (0%)	0 (0%)	1 (0.5%)	1 (1.4%)	2 (0.2%)
Selective eating disorder	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Spinal pain	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)

Strabismus	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Suture rupture	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Symphysiolysis	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Toxoplasmosis	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Trigeminal neuralgia	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Uterine cervical laceration	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Uterine leiomyoma	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Vaginal infection	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Vaginal perforation	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Vertigo	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Viral myocarditis	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Weight abnormal	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
Wolff-Parkinson-White syndrome	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
B-lymphocyte count decreased	0 (0%)	0 (0%)	0 (0%)	1 (1.4%)	1 (0.1%)
Blindness unilateral	0 (0%)	0 (0%)	0 (0%)	1 (1.4%)	1 (0.1%)
Burning sensation	0 (0%)	0 (0%)	0 (0%)	1 (1.4%)	1 (0.1%)
COVID-19 pneumonia	0 (0%)	0 (0%)	0 (0%)	2 (2.9%)	2 (0.2%)
Cystitis bacterial	0 (0%)	0 (0%)	0 (0%)	1 (1.4%)	1 (0.1%)
Decreased embryo viability	0 (0%)	0 (0%)	0 (0%)	1 (1.4%)	1 (0.1%)
Desmoid tumour	0 (0%)	0 (0%)	0 (0%)	1 (1.4%)	1 (0.1%)
Dysphagia	0 (0%)	0 (0%)	0 (0%)	1 (1.4%)	1 (0.1%)
Erythema multiforme	0 (0%)	0 (0%)	0 (0%)	1 (1.4%)	1 (0.1%)
Fungal infection	0 (0%)	0 (0%)	0 (0%)	1 (1.4%)	1 (0.1%)
Immunoglobulins decreased	0 (0%)	0 (0%)	0 (0%)	1 (1.4%)	1 (0.1%)
Injury	0 (0%)	0 (0%)	0 (0%)	1 (1.4%)	1 (0.1%)
Jaundice	0 (0%)	0 (0%)	0 (0%)	2 (2.9%)	2 (0.2%)
Liver function test abnormal	0 (0%)	0 (0%)	0 (0%)	1 (1.4%)	1 (0.1%)
Macrosomia	0 (0%)	0 (0%)	0 (0%)	1 (1.4%)	1 (0.1%)
Muscle spasticity	0 (0%)	0 (0%)	0 (0%)	1 (1.4%)	1 (0.1%)
Muscle twitching	0 (0%)	0 (0%)	0 (0%)	1 (1.4%)	1 (0.1%)
Neuromyelitis optica spectrum disorder	0 (0%)	0 (0%)	0 (0%)	1 (1.4%)	1 (0.1%)
Pneumonia bacterial	0 (0%)	0 (0%)	0 (0%)	1 (1.4%)	1 (0.1%)

Psoriasis	0 (0%)	0 (0%)	0 (0%)	1 (1.4%)	1 (0.1%)
Seizure	0 (0%)	0 (0%)	0 (0%)	1 (1.4%)	1 (0.1%)
Somatic symptom disorder of pregnancy	0 (0%)	0 (0%)	0 (0%)	1 (1.4%)	1 (0.1%)
Swelling of eyelid	0 (0%)	0 (0%)	0 (0%)	1 (1.4%)	1 (0.1%)
Throat irritation	0 (0%)	0 (0%)	0 (0%)	1 (1.4%)	1 (0.1%)

Part II – Termination of pregnancy and risk of abortion

Termination of pregnancy and risk of abortion	**ALEMTUZUMAB (N=20)**	**GLATIRAMER (N=55)**	**NATALIZUMAB (N=266)**	**OCRELIZUMAB (N=38)**	**Overall (N=379)**
Abortion	2 (10.0%)	6 (10.9%)	8 (3.0%)	0 (0%)	16 (4.2%)
Abortion incomplete	3 (15.0%)	0 (0%)	0 (0%)	0 (0%)	3 (0.8%)
Abortion induced	0 (0%)	2 (3.6%)	4 (1.5%)	0 (0%)	6 (1.6%)
Abortion missed	0 (0%)	3 (5.5%)	6 (2.3%)	3 (7.9%)	12 (3.2%)
Abortion of ectopic pregnancy	0 (0%)	0 (0%)	1 (0.4%)	0 (0%)	1 (0.3%)
Abortion spontaneous	13 (65.0%)	42 (76.4%)	235 (88.3%)	31 (81.6%)	321 (84.7%)
Abortion spontaneous complete	1 (5.0%)	0 (0%)	0 (0%)	0 (0%)	1 (0.3%)
Abortion threatened	0 (0%)	0 (0%)	3 (1.1%)	0 (0%)	3 (0.8%)
Anembryonic gestation	0 (0%)	1 (1.8%)	2 (0.8%)	0 (0%)	3 (0.8%)
Foetal death	1 (5.0%)	1 (1.8%)	2 (0.8%)	2 (5.3%)	6 (1.6%)
Habitual abortion	0 (0%)	0 (0%)	0 (0%)	1 (2.6%)	1 (0.3%)
Stillbirth	0 (0%)	0 (0%)	5 (1.9%)	1 (2.6%)	6 (1.6%)

Part III - Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth)

Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth)	ALEMTUZUMAB (N=7)	GLATIRAMER (N=54)	NATALIZUMAB (N=284)	OCRELIZUMAB (N=15)	Overall (N=360)
Abnormal labour	0 (0%)	0 (0%)	1 (0.1%)	0 (0%)	1 (0.3%)
Amniotic cavity infection	0 (0%)	0 (0%)	3 (0.3%)	1 (1.0%)	4 (1.1%)
Amniotic fluid volume decreased	0 (0%)	2 (0.8%)	2 (0.2%)	0 (0%)	4 (1.1%)
Anaemia of pregnancy	0 (0%)	0 (0%)	2 (0.2%)	0 (0%)	2 (0.6%)
Assisted delivery	0 (0%)	0 (0%)	1 (0.1%)	0 (0%)	1 (0.3%)
Bacteriuria in pregnancy	0 (0%)	0 (0%)	1 (0.1%)	0 (0%)	1 (0.3%)
Benign hydatidiform mole	0 (0%)	0 (0%)	1 (0.1%)	0 (0%)	1 (0.3%)
Breech presentation	0 (0%)	1 (0.4%)	7 (0.7%)	0 (0%)	8 (2.2%)
Caesarean section	0 (0%)	13 (5.5%)	93 (8.8%)	0 (0%)	106 (29.5%)
Cephalo-pelvic disproportion	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.3%)
Cervical incompetence	1 (1.4%)	1 (0.4%)	4 (0.4%)	0 (0%)	6 (1.7%)
Cervix dystocia	0 (0%)	0 (0%)	2 (0.2%)	0 (0%)	2 (0.6%)
Cholestasis of pregnancy	0 (0%)	0 (0%)	4 (0.4%)	0 (0%)	4 (1.1%)
Complication of delivery	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.3%)
Complication of pregnancy	0 (0%)	0 (0%)	3 (0.3%)	0 (0%)	3 (0.8%)
Ectopic pregnancy	2 (2.8%)	3 (1.3%)	9 (0.9%)	0 (0%)	14 (3.9%)
Face presentation	0 (0%)	0 (0%)	1 (0.1%)	0 (0%)	1 (0.3%)
Failed induction of labour	0 (0%)	0 (0%)	1 (0.1%)	0 (0%)	1 (0.3%)
Foetal malposition	0 (0%)	1 (0.4%)	5 (0.5%)	0 (0%)	6 (1.7%)
Foetal malpresentation	0 (0%)	0 (0%)	1 (0.1%)	0 (0%)	1 (0.3%)
Gestational diabetes	1 (1.4%)	6 (2.5%)	8 (0.8%)	3 (2.9%)	18 (5.0%)
Gestational hypertension	0 (0%)	1 (0.4%)	2 (0.2%)	0 (0%)	3 (0.8%)
Haemorrhage in pregnancy	0 (0%)	2 (0.8%)	8 (0.8%)	0 (0%)	10 (2.8%)
HELLP syndrome	0 (0%)	0 (0%)	3 (0.3%)	0 (0%)	3 (0.8%)
High risk pregnancy	0 (0%)	0 (0%)	1 (0.1%)	0 (0%)	1 (0.3%)

Hyperemesis gravidarum	0 (0%)	2 (0.8%)	4 (0.4%)	0 (0%)	6 (1.7%)
Intrapartum haemorrhage	0 (0%)	0 (0%)	1 (0.1%)	0 (0%)	1 (0.3%)
Labour complication	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.3%)
Large for dates baby	0 (0%)	1 (0.4%)	2 (0.2%)	0 (0%)	3 (0.8%)
Morning sickness	2 (2.8%)	1 (0.4%)	0 (0%)	0 (0%)	3 (0.8%)
Oblique presentation	0 (0%)	0 (0%)	1 (0.1%)	0 (0%)	1 (0.3%)
Obstructed labour	0 (0%)	0 (0%)	1 (0.1%)	0 (0%)	1 (0.3%)
Oligohydramnios	0 (0%)	1 (0.4%)	2 (0.2%)	1 (1.0%)	4 (1.1%)
Perineal injury	0 (0%)	0 (0%)	4 (0.4%)	0 (0%)	4 (1.1%)
Placenta praevia	0 (0%)	0 (0%)	2 (0.2%)	0 (0%)	2 (0.6%)
Placental disorder	0 (0%)	0 (0%)	3 (0.3%)	0 (0%)	3 (0.8%)
Placental infarction	0 (0%)	0 (0%)	1 (0.1%)	0 (0%)	1 (0.3%)
Placental insufficiency	0 (0%)	0 (0%)	3 (0.3%)	0 (0%)	3 (0.8%)
Placental transfusion syndrome	0 (0%)	0 (0%)	3 (0.3%)	0 (0%)	3 (0.8%)
Polyhydramnios	0 (0%)	0 (0%)	0 (0%)	1 (1.0%)	1 (0.3%)
Polymorphic eruption of pregnancy	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.3%)
Postpartum haemorrhage	0 (0%)	0 (0%)	2 (0.2%)	0 (0%)	2 (0.6%)
Precipitate labour	0 (0%)	0 (0%)	1 (0.1%)	0 (0%)	1 (0.3%)
Pre-eclampsia	0 (0%)	1 (0.4%)	16 (1.5%)	0 (0%)	17 (4.7%)
Pregnancy with advanced maternal age	0 (0%)	0 (0%)	1 (0.1%)	0 (0%)	1 (0.3%)
Premature delivery	0 (0%)	2 (0.8%)	35 (3.3%)	3 (2.9%)	40 (11.1%)
Premature labour	0 (0%)	4 (1.7%)	5 (0.5%)	1 (1.0%)	10 (2.8%)
Premature rupture of membranes	0 (0%)	1 (0.4%)	6 (0.6%)	1 (1.0%)	8 (2.2%)
Premature separation of placenta	0 (0%)	0 (0%)	5 (0.5%)	0 (0%)	5 (1.4%)
Preterm premature rupture of membranes	0 (0%)	1 (0.4%)	1 (0.1%)	0 (0%)	2 (0.6%)
Prolonged labour	0 (0%)	3 (1.3%)	7 (0.7%)	0 (0%)	10 (2.8%)
Prolonged pregnancy	0 (0%)	0 (0%)	1 (0.1%)	0 (0%)	1 (0.3%)
Retained placenta or membranes	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.3%)
Small size placenta	0 (0%)	0 (0%)	2 (0.2%)	0 (0%)	2 (0.6%)

Subchorionic haematoma	0 (0%)	0 (0%)	1 (0.1%)	0 (0%)	1 (0.3%)
Transverse presentation	0 (0%)	0 (0%)	1 (0.1%)	0 (0%)	1 (0.3%)
Twin pregnancy	0 (0%)	0 (0%)	1 (0.1%)	2 (2.0%)	3 (0.8%)
Umbilical cord abnormality	0 (0%)	1 (0.4%)	2 (0.2%)	2 (2.0%)	5 (1.4%)
Umbilical cord around neck	1 (1.4%)	0 (0%)	2 (0.2%)	0 (0%)	3 (0.8%)
Umbilical cord cyst	0 (0%)	0 (0%)	1 (0.1%)	0 (0%)	1 (0.3%)
Uterine contractions abnormal	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.3%)
Uterine hypotonus	0 (0%)	0 (0%)	1 (0.1%)	0 (0%)	1 (0.3%)
Uterine rupture	0 (0%)	0 (0%)	1 (0.1%)	0 (0%)	1 (0.3%)
Vulvovaginal injury	0 (0%)	0 (0%)	2 (0.2%)	0 (0%)	2 (0.6%)

Part IV - Neonatal disorders

Neonatal disorders	ALEMTUZUMAB (N=8)	GLATIRAMER (N=18)	NATALIZUMAB (N=130)	OCRELIZUMAB (N=6)	Overall (N=162)
Anaemia neonatal	0 (0%)	0 (0%)	16 (12.3%)	1 (16.7%)	17 (10.5%)
Apgar score low	0 (0%)	1 (5.6%)	0 (0%)	0 (0%)	1 (0.6%)
Arrhythmia neonatal	0 (0%)	1 (5.6%)	1 (0.8%)	0 (0%)	2 (1.2%)
Cyanosis neonatal	0 (0%)	0 (0%)	1 (0.8%)	0 (0%)	1 (0.6%)
Death neonatal	0 (0%)	0 (0%)	3 (2.3%)	0 (0%)	3 (1.9%)
Disturbance of thermoregulation of newborn	0 (0%)	0 (0%)	1 (0.8%)	0 (0%)	1 (0.6%)
Fever neonatal	0 (0%)	0 (0%)	1 (0.8%)	0 (0%)	1 (0.6%)
Hypoglycaemia neonatal	1 (12.5%)	1 (5.6%)	1 (0.8%)	0 (0%)	3 (1.9%)

Hypotonia neonatal	1 (12.5%)	0 (0%)	0 (0%)	0 (0%)	1 (0.6%)
Infantile apnoea	0 (0%)	0 (0%)	1 (0.8%)	0 (0%)	1 (0.6%)
Infantile haemangioma	0 (0%)	1 (5.6%)	0 (0%)	0 (0%)	1 (0.6%)
Intraventricular haemorrhage neonatal	1 (12.5%)	0 (0%)	0 (0%)	0 (0%)	1 (0.6%)
Jaundice neonatal	0 (0%)	1 (5.6%)	5 (3.8%)	0 (0%)	6 (3.7%)
Low birth weight baby	0 (0%)	1 (5.6%)	24 (18.5%)	0 (0%)	25 (15.4%)
Maternal exposure during delivery	0 (0%)	1 (5.6%)	0 (0%)	0 (0%)	1 (0.6%)
Meningitis neonatal	0 (0%)	0 (0%)	3 (2.3%)	0 (0%)	3 (1.9%)
Myasthenia gravis neonatal	2 (25.0%)	0 (0%)	0 (0%)	0 (0%)	2 (1.2%)
Neonatal anoxia	0 (0%)	1 (5.6%)	0 (0%)	0 (0%)	1 (0.6%)
Neonatal asphyxia	0 (0%)	0 (0%)	1 (0.8%)	0 (0%)	1 (0.6%)
Neonatal behavioural syndrome	1 (12.5%)	0 (0%)	0 (0%)	0 (0%)	1 (0.6%)
Neonatal cardiac failure	0 (0%)	0 (0%)	1 (0.8%)	0 (0%)	1 (0.6%)
Neonatal gastrointestinal disorder	0 (0%)	0 (0%)	1 (0.8%)	0 (0%)	1 (0.6%)
Neonatal hypoacusis	0 (0%)	0 (0%)	1 (0.8%)	0 (0%)	1 (0.6%)
Neonatal hypoxia	0 (0%)	1 (5.6%)	0 (0%)	0 (0%)	1 (0.6%)
Neonatal infection	0 (0%)	0 (0%)	2 (1.5%)	0 (0%)	2 (1.2%)
Neonatal multi-organ failure	0 (0%)	0 (0%)	1 (0.8%)	0 (0%)	1 (0.6%)
Neonatal pneumothorax	0 (0%)	0 (0%)	0 (0%)	1 (16.7%)	1 (0.6%)
Neonatal respiratory distress	0 (0%)	1 (5.6%)	1 (0.8%)	0 (0%)	2 (1.2%)
Neonatal respiratory distress syndrome	0 (0%)	0 (0%)	1 (0.8%)	0 (0%)	1 (0.6%)
Neonatal respiratory failure	0 (0%)	0 (0%)	1 (0.8%)	0 (0%)	1 (0.6%)
Neonatal thyrotoxicosis	1 (12.5%)	0 (0%)	0 (0%)	0 (0%)	1 (0.6%)
Perinatal brain damage	0 (0%)	0 (0%)	1 (0.8%)	0 (0%)	1 (0.6%)
Poor feeding infant	0 (0%)	0 (0%)	2 (1.5%)	0 (0%)	2 (1.2%)
Poor sucking reflex	0 (0%)	0 (0%)	2 (1.5%)	0 (0%)	2 (1.2%)
Poor weight gain neonatal	0 (0%)	1 (5.6%)	0 (0%)	0 (0%)	1 (0.6%)
Premature baby	1 (12.5%)	5 (27.8%)	52 (40.0%)	4 (66.7%)	62 (38.3%)
Pulmonary oedema neonatal	0 (0%)	0 (0%)	1 (0.8%)	0 (0%)	1 (0.6%)

Respiratory disorder neonatal	0 (0%)	0 (0%)	1 (0.8%)	0 (0%)	1 (0.6%)
Sepsis neonatal	0 (0%)	1 (5.6%)	0 (0%)	0 (0%)	1 (0.6%)
Small for dates baby	0 (0%)	1 (5.6%)	2 (1.5%)	0 (0%)	3 (1.9%)
Thrombocytopenia neonatal	0 (0%)	0 (0%)	2 (1.5%)	0 (0%)	2 (1.2%)

Part V - Congenital, familial and genetic disorders

Congenital, familial and genetic disorders	**ALEMTUZUMAB (n=8)**	**GLATIRAMER (n=23)**	**NATALIZUMAB (n=103)**	**OCRELIZUMAB (n=5)**	**Overall (n=139)**
Accessory spleen	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Adactyly	0 (0%)	1 (4.3%)	0 (0%)	0 (0%)	1 (0.7%)
Amniotic band syndrome	0 (0%)	1 (4.3%)	1 (1.0%)	0 (0%)	2 (1.4%)
Anencephaly	0 (0%)	0 (0%)	2 (1.9%)	0 (0%)	2 (1.4%)
Ankyloglossia congenital	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Anomaly of external ear congenital	1 (12.5%)	0 (0%)	0 (0%)	0 (0%)	1 (0.7%)
Aorta hypoplasia	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Atrial septal defect	1 (12.5%)	2 (8.7%)	3 (2.9%)	0 (0%)	6 (4.3%)
Atrioventricular septal defect	0 (0%)	1 (4.3%)	0 (0%)	0 (0%)	1 (0.7%)
Autosomal chromosome anomaly	0 (0%)	0 (0%)	2 (1.9%)	0 (0%)	2 (1.4%)
Benign congenital hypotonia	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Brachydactyly	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Brain malformation	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Cardiac malposition	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Cardiac septal defect	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Cerebellar hypoplasia	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Cleft lip and palate	0 (0%)	2 (8.7%)	0 (0%)	0 (0%)	2 (1.4%)

Cleft palate	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Congenital anaemia	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Congenital anomaly	0 (0%)	0 (0%)	14 (13.6%)	0 (0%)	14 (10.1%)
Congenital anomaly of inner ear	0 (0%)	1 (4.3%)	0 (0%)	0 (0%)	1 (0.7%)
Congenital aortic anomaly	0 (0%)	1 (4.3%)	0 (0%)	0 (0%)	1 (0.7%)
Congenital cardiovascular anomaly	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Congenital central nervous system anomaly	0 (0%)	0 (0%)	2 (1.9%)	0 (0%)	2 (1.4%)
Congenital cerebral cyst	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Congenital cystic kidney disease	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Congenital cytomegalovirus infection	1 (12.5%)	0 (0%)	0 (0%)	0 (0%)	1 (0.7%)
Congenital diaphragmatic hernia	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Congenital foot malformation	0 (0%)	1 (4.3%)	0 (0%)	0 (0%)	1 (0.7%)
Congenital gastric anomaly	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Congenital hearing disorder	0 (0%)	1 (4.3%)	0 (0%)	0 (0%)	1 (0.7%)
Congenital heart valve incompetence	0 (0%)	0 (0%)	0 (0%)	1 (20.0%)	1 (0.7%)
Congenital hydrocephalus	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Congenital hyperthyroidism	1 (12.5%)	0 (0%)	0 (0%)	0 (0%)	1 (0.7%)
Congenital hypothyroidism	1 (12.5%)	0 (0%)	0 (0%)	0 (0%)	1 (0.7%)
Congenital megacolon	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Congenital naevus	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Congenital pulmonary artery anomaly	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Congenital pyelocaliectasis	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Congenital renal disorder	0 (0%)	0 (0%)	1 (1.0%)	1 (20.0%)	2 (1.4%)
Congenital skin disorder	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Congenital thrombocytopenia	0 (0%)	0 (0%)	2 (1.9%)	0 (0%)	2 (1.4%)
Congenital tricuspid valve atresia	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Cryptorchism	0 (0%)	1 (4.3%)	0 (0%)	0 (0%)	1 (0.7%)
Cytogenetic abnormality	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Deafness congenital	0 (0%)	1 (4.3%)	0 (0%)	0 (0%)	1 (0.7%)

Double outlet right ventricle	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Exomphalos	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Fallot's tetralogy	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Gastroschisis	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Gnathoschisis	0 (0%)	1 (4.3%)	0 (0%)	0 (0%)	1 (0.7%)
Heart disease congenital	0 (0%)	0 (0%)	3 (2.9%)	0 (0%)	3 (2.2%)
Heterotaxia	0 (0%)	0 (0%)	2 (1.9%)	0 (0%)	2 (1.4%)
Hypospadias	0 (0%)	1 (4.3%)	1 (1.0%)	0 (0%)	2 (1.4%)
Kidney malformation	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Kinematic imbalances due to suboccipital strain	0 (0%)	1 (4.3%)	0 (0%)	0 (0%)	1 (0.7%)
Macrocephaly	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Meningocele	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Microcephaly	1 (12.5%)	0 (0%)	0 (0%)	0 (0%)	1 (0.7%)
Neuronal migration disorder	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Otospondylomegaepiphyseal dysplasia	0 (0%)	1 (4.3%)	1 (1.0%)	0 (0%)	2 (1.4%)
Patent ductus arteriosus	0 (0%)	1 (4.3%)	2 (1.9%)	0 (0%)	3 (2.2%)
Phenylketonuria	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Polydactyly	0 (0%)	2 (8.7%)	0 (0%)	1 (20.0%)	3 (2.2%)
Porencephaly	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Pulmonary artery atresia	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Pulmonary sequestration	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Pyloric stenosis	2 (25.0%)	0 (0%)	0 (0%)	0 (0%)	2 (1.4%)
Renal aplasia	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Respiratory tract malformation	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Right aortic arch	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Single umbilical artery	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Skin hypoplasia	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Spina bifida	0 (0%)	1 (4.3%)	0 (0%)	0 (0%)	1 (0.7%)
Syndactyly	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)

Talipes	0 (0%)	0 (0%)	4 (3.9%)	0 (0%)	4 (2.9%)
Thalassaemia alpha	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Thyroglossal cyst	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Transposition of the great vessels	0 (0%)	1 (4.3%)	0 (0%)	0 (0%)	1 (0.7%)
Trisomy 13	0 (0%)	0 (0%)	2 (1.9%)	0 (0%)	2 (1.4%)
Trisomy 18	0 (0%)	0 (0%)	3 (2.9%)	0 (0%)	3 (2.2%)
Trisomy 21	0 (0%)	0 (0%)	6 (5.8%)	1 (20.0%)	7 (5.0%)
Trisomy 9	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Turner's syndrome	0 (0%)	0 (0%)	2 (1.9%)	0 (0%)	2 (1.4%)
Urethral valves	0 (0%)	0 (0%)	0 (0%)	1 (20.0%)	1 (0.7%)
Ventricular hypoplasia	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	1 (0.7%)
Ventricular septal defect	0 (0%)	1 (4.3%)	4 (3.9%)	0 (0%)	5 (3.6%)

Part VI - Neonatal other ADRs

Neonatal other ADR	ALEMTUZUMAB (N=18)	GLATIRAMER (N=3)	NATALIZUMAB (N=56)	OCRELIZUMAB (N=12)	Overall (N=89)
Adenovirus infection	1 (5.6%)	0 (0%)	0 (0%)	0 (0%)	1 (1.1%)
Agitation	1 (5.6%)	0 (0%)	0 (0%)	0 (0%)	1 (1.1%)
Anaemia	0 (0%)	0 (0%)	4 (7.1%)	0 (0%)	4 (4.4%)
Anti-thyroid antibody positive	2 (11.1%)	0 (0%)	0 (0%)	0 (0%)	2 (2.2%)
Areflexia	1 (5.6%)	0 (0%)	0 (0%)	0 (0%)	1 (1.1%)
Arthropathy	0 (0%)	0 (0%)	1 (1.8%)	0 (0%)	1 (1.1%)
Autism spectrum disorder	0 (0%)	0 (0%)	2 (3.6%)	0 (0%)	2 (2.2%)

Blood bilirubin decreased	0 (0%)	0 (0%)	1 (1.8%)	0 (0%)	1 (1.1%)
Blood glucose decreased	0 (0%)	0 (0%)	0 (0%)	1 (8.3%)	1 (1.1%)
Blood test abnormal	0 (0%)	0 (0%)	1 (1.8%)	0 (0%)	1 (1.1%)
Cardiac failure	0 (0%)	0 (0%)	1 (1.8%)	0 (0%)	1 (1.1%)
Cardiac murmur	0 (0%)	0 (0%)	2 (3.6%)	0 (0%)	2 (2.2%)
Cerebrovascular accident	0 (0%)	0 (0%)	0 (0%)	1 (8.3%)	1 (1.1%)
Congenital musculoskeletal disorder	0 (0%)	0 (0%)	0 (0%)	1 (8.3%)	1 (1.1%)
Constipation	0 (0%)	0 (0%)	1 (1.8%)	0 (0%)	1 (1.1%)
Cystic lung disease	0 (0%)	0 (0%)	1 (1.8%)	0 (0%)	1 (1.1%)
Cytomegalovirus infection reactivation	1 (5.6%)	0 (0%)	0 (0%)	0 (0%)	1 (1.1%)
Enterococcus test positive	0 (0%)	0 (0%)	1 (1.8%)	0 (0%)	1 (1.1%)
Escherichia sepsis	0 (0%)	0 (0%)	1 (1.8%)	0 (0%)	1 (1.1%)
Eyelid disorder	0 (0%)	0 (0%)	0 (0%)	1 (8.3%)	1 (1.1%)
Feeding disorder	0 (0%)	0 (0%)	1 (1.8%)	0 (0%)	1 (1.1%)
Fluid intake reduced	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1.1%)
Foot deformity	0 (0%)	0 (0%)	1 (1.8%)	0 (0%)	1 (1.1%)
Granulocyte count decreased	0 (0%)	0 (0%)	1 (1.8%)	0 (0%)	1 (1.1%)
Haemangioma	0 (0%)	0 (0%)	2 (3.6%)	0 (0%)	2 (2.2%)
Haematochezia	0 (0%)	0 (0%)	1 (1.8%)	0 (0%)	1 (1.1%)
Haemoglobin abnormal	0 (0%)	0 (0%)	1 (1.8%)	0 (0%)	1 (1.1%)
Haemoglobin decreased	0 (0%)	0 (0%)	1 (1.8%)	0 (0%)	1 (1.1%)
Heart rate decreased	0 (0%)	0 (0%)	0 (0%)	1 (8.3%)	1 (1.1%)
Hypertension	1 (5.6%)	0 (0%)	0 (0%)	0 (0%)	1 (1.1%)
Hyponatraemia	1 (5.6%)	0 (0%)	0 (0%)	0 (0%)	1 (1.1%)
Hypophagia	0 (0%)	0 (0%)	1 (1.8%)	0 (0%)	1 (1.1%)
Hypotonia	0 (0%)	1 (33.3%)	0 (0%)	0 (0%)	1 (1.1%)
Ileal perforation	0 (0%)	0 (0%)	1 (1.8%)	0 (0%)	1 (1.1%)
Infection	0 (0%)	0 (0%)	1 (1.8%)	0 (0%)	1 (1.1%)
Inguinal hernia	1 (5.6%)	0 (0%)	0 (0%)	0 (0%)	1 (1.1%)

Jaundice	0 (0%)	0 (0%)	1 (1.8%)	0 (0%)	1 (1.1%)
Leukocytosis	0 (0%)	0 (0%)	1 (1.8%)	0 (0%)	1 (1.1%)
Long QT syndrome	0 (0%)	0 (0%)	0 (0%)	1 (8.3%)	1 (1.1%)
Loss of consciousness	0 (0%)	1 (33.3%)	0 (0%)	0 (0%)	1 (1.1%)
Meningitis bacterial	0 (0%)	0 (0%)	1 (1.8%)	0 (0%)	1 (1.1%)
Mitral valve incompetence	1 (5.6%)	0 (0%)	0 (0%)	0 (0%)	1 (1.1%)
Multiple organ dysfunction syndrome	0 (0%)	1 (33.3%)	0 (0%)	0 (0%)	1 (1.1%)
Muscle tone disorder	1 (5.6%)	0 (0%)	0 (0%)	0 (0%)	1 (1.1%)
Oxygen saturation decreased	0 (0%)	0 (0%)	1 (1.8%)	0 (0%)	1 (1.1%)
Pancreatitis	1 (5.6%)	0 (0%)	0 (0%)	0 (0%)	1 (1.1%)
Petechiae	0 (0%)	0 (0%)	1 (1.8%)	0 (0%)	1 (1.1%)
Platelet count decreased	0 (0%)	0 (0%)	3 (5.4%)	0 (0%)	3 (3.3%)
Pneumonia	0 (0%)	0 (0%)	0 (0%)	1 (8.3%)	1 (1.1%)
Pneumothorax	0 (0%)	0 (0%)	0 (0%)	1 (8.3%)	1 (1.1%)
Posterior reversible encephalopathy syndrome	1 (5.6%)	0 (0%)	0 (0%)	0 (0%)	1 (1.1%)
Pulmonary arterial hypertension	0 (0%)	0 (0%)	1 (1.8%)	0 (0%)	1 (1.1%)
Pulmonary sepsis	0 (0%)	0 (0%)	0 (0%)	1 (8.3%)	1 (1.1%)
Pulmonary valve stenosis	0 (0%)	0 (0%)	2 (3.6%)	0 (0%)	2 (2.2%)
Pulmonary vein stenosis	0 (0%)	0 (0%)	1 (1.8%)	0 (0%)	1 (1.1%)
Reduced facial expression	1 (5.6%)	0 (0%)	0 (0%)	0 (0%)	1 (1.1%)
Respiratory disorder	1 (5.6%)	0 (0%)	0 (0%)	0 (0%)	1 (1.1%)
Respiratory distress	0 (0%)	0 (0%)	0 (0%)	1 (8.3%)	1 (1.1%)
Respiratory failure	0 (0%)	0 (0%)	1 (1.8%)	0 (0%)	1 (1.1%)
Respiratory syncytial virus bronchiolitis	0 (0%)	0 (0%)	0 (0%)	1 (8.3%)	1 (1.1%)
Retinal haemorrhage	0 (0%)	0 (0%)	1 (1.8%)	0 (0%)	1 (1.1%)
Seizure	0 (0%)	0 (0%)	1 (1.8%)	0 (0%)	1 (1.1%)
Sepsis	0 (0%)	0 (0%)	0 (0%)	1 (8.3%)	1 (1.1%)
Serum ferritin increased	0 (0%)	0 (0%)	1 (1.8%)	0 (0%)	1 (1.1%)
Short stature	1 (5.6%)	0 (0%)	0 (0%)	0 (0%)	1 (1.1%)

Staphylococcus test positive	0 (0%)	0 (0%)	1 (1.8%)	0 (0%)	1 (1.1%)
Tachycardia	1 (5.6%)	0 (0%)	0 (0%)	0 (0%)	1 (1.1%)
Thrombocytopenia	0 (0%)	0 (0%)	9 (16.1%)	0 (0%)	9 (10.0%)
Weight decreased	0 (0%)	0 (0%)	1 (1.8%)	0 (0%)	1 (1.1%)
Weight gain poor	0 (0%)	0 (0%)	1 (1.8%)	0 (0%)	1 (1.1%)
White blood cell disorder	0 (0%)	0 (0%)	1 (1.8%)	0 (0%)	1 (1.1%)
Wound infection	1 (5.6%)	0 (0%)	0 (0%)	0 (0%)	1 (1.1%)

Part VII – Foetal disorders

Foetal disorders	**ALEMTUZUMAB (N=4)**	**GLATIRAMER (N=12)**	**NATALIZUMAB (N=36)**	**OCRELIZUMAB (N=1)**	**Overall (N=53)**
Bradycardia foetal	0 (0%)	0 (0%)	2 (5.6%)	0 (0%)	2 (3.8%)
Foetal anaemia	0 (0%)	0 (0%)	3 (8.3%)	0 (0%)	3 (5.7%)
Foetal disorder	1 (25.0%)	0 (0%)	2 (5.6%)	0 (0%)	3 (5.7%)
Foetal distress syndrome	0 (0%)	0 (0%)	4 (11.1%)	0 (0%)	4 (7.5%)
Foetal growth restriction	3 (75.0%)	5 (41.7%)	10 (27.8%)	1 (100%)	19 (35.8%)
Foetal heart rate abnormal	0 (0%)	2 (16.7%)	5 (13.9%)	0 (0%)	7 (13.2%)
Foetal heart rate deceleration abnormality	0 (0%)	0 (0%)	2 (5.6%)	0 (0%)	2 (3.8%)
Foetal heart rate decreased	0 (0%)	2 (16.7%)	1 (2.8%)	0 (0%)	3 (5.7%)
Foetal malformation	0 (0%)	2 (16.7%)	5 (13.9%)	0 (0%)	7 (13.2%)
Hydrops foetalis	0 (0%)	0 (0%)	2 (5.6%)	0 (0%)	2 (3.8%)
Meconium in amniotic fluid	0 (0%)	1 (8.3%)	0 (0%)	0 (0%)	1 (1.9%)

Part VIII - Infant other ADRs

Infant other ADR	ALEMTUZUMAB (N=5)	GLATIRAMER (N=9)	NATALIZUMAB (N=20)	OCRELIZUMAB (N=10)	Overall (N=44)
Anaemia	0 (0%)	0 (0%)	3 (15.0%)	0 (0%)	3 (6.8%)
Autism spectrum disorder	0 (0%)	0 (0%)	3 (15.0%)	0 (0%)	3 (6.8%)
Autoimmune neutropenia	0 (0%)	0 (0%)	1 (5.0%)	0 (0%)	1 (2.3%)
Blood thyroid stimulating hormone decreased	2 (40.0%)	0 (0%)	0 (0%)	0 (0%)	2 (4.5%)
Bronchitis	0 (0%)	1 (11.1%)	0 (0%)	0 (0%)	1 (2.3%)
Cough	0 (0%)	0 (0%)	1 (5.0%)	0 (0%)	1 (2.3%)
COVID-19	0 (0%)	2 (22.2%)	0 (0%)	1 (10.0%)	3 (6.8%)
Deafness unilateral	0 (0%)	0 (0%)	1 (5.0%)	0 (0%)	1 (2.3%)
Enterococcal infection	0 (0%)	0 (0%)	0 (0%)	1 (10.0%)	1 (2.3%)
Gastroenteritis	0 (0%)	0 (0%)	1 (5.0%)	1 (10.0%)	2 (4.5%)
Haemangioma of skin	0 (0%)	0 (0%)	1 (5.0%)	0 (0%)	1 (2.3%)
Heart sounds abnormal	0 (0%)	1 (11.1%)	0 (0%)	0 (0%)	1 (2.3%)
Hypersensitivity	0 (0%)	0 (0%)	1 (5.0%)	0 (0%)	1 (2.3%)
Infection	0 (0%)	1 (11.1%)	0 (0%)	0 (0%)	1 (2.3%)
Influenza	0 (0%)	0 (0%)	0 (0%)	1 (10.0%)	1 (2.3%)
Lactose intolerance	0 (0%)	0 (0%)	1 (5.0%)	0 (0%)	1 (2.3%)
Malaise	0 (0%)	0 (0%)	0 (0%)	1 (10.0%)	1 (2.3%)
Myoclonic epilepsy	0 (0%)	0 (0%)	1 (5.0%)	0 (0%)	1 (2.3%)
Normal newborn	0 (0%)	0 (0%)	1 (5.0%)	0 (0%)	1 (2.3%)
Pain	0 (0%)	0 (0%)	0 (0%)	1 (10.0%)	1 (2.3%)
Pyelonephritis	0 (0%)	0 (0%)	1 (5.0%)	0 (0%)	1 (2.3%)
Pyrexia	0 (0%)	1 (11.1%)	0 (0%)	1 (10.0%)	2 (4.5%)
Respiratory syncytial virus infection	0 (0%)	0 (0%)	0 (0%)	1 (10.0%)	1 (2.3%)
Sensitisation	0 (0%)	0 (0%)	1 (5.0%)	0 (0%)	1 (2.3%)
Speech disorder developmental	0 (0%)	0 (0%)	1 (5.0%)	0 (0%)	1 (2.3%)

Staphylococcal infection	0 (0%)	0 (0%)	0 (0%)	1 (10.0%)	1 (2.3%)
Stridor	0 (0%)	1 (11.1%)	0 (0%)	0 (0%)	1 (2.3%)
Thrombocytopenia	0 (0%)	0 (0%)	1 (5.0%)	0 (0%)	1 (2.3%)
Thyroid disorder	1 (20.0%)	0 (0%)	0 (0%)	0 (0%)	1 (2.3%)
Thyroid function test abnormal	2 (40.0%)	0 (0%)	0 (0%)	0 (0%)	2 (4.5%)
Underweight	0 (0%)	0 (0%)	1 (5.0%)	0 (0%)	1 (2.3%)
Viral infection	0 (0%)	1 (11.1%)	0 (0%)	0 (0%)	1 (2.3%)
Vomiting	0 (0%)	0 (0%)	0 (0%)	1 (10.0%)	1 (2.3%)
Weight gain poor	0 (0%)	1 (11.1%)	0 (0%)	0 (0%)	1 (2.3%)

Part IX - Foetal other ADRs

Foetal disorders	ALEMTUZUMAB (N=6)	GLATIRAMER (N=0)	NATALIZUMAB (N=0)	OCRELIZUMAB (N=4)	Overall (N=10)
Bladder dilatation	0 (0%)	0 (0%)	0 (0%)	1 (25.0%)	1 (10.0%)
Cerebral calcification	1 (16.7%)	0 (0%)	0 (0%)	0 (0%)	1 (10.0%)
Cerebral cyst	1 (16.7%)	0 (0%)	0 (0%)	0 (0%)	1 (10.0%)
Cerebral ventricle dilatation	1 (16.7%)	0 (0%)	0 (0%)	0 (0%)	1 (10.0%)
Congenital musculoskeletal disorder of skull	0 (0%)	0 (0%)	0 (0%)	1 (25.0%)	1 (10.0%)
Deafness unilateral	1 (16.7%)	0 (0%)	0 (0%)	0 (0%)	1 (10.0%)
Hydronephrosis	0 (0%)	0 (0%)	0 (0%)	1 (25.0%)	1 (10.0%)
Hyperthyroidism	1 (16.7%)	0 (0%)	0 (0%)	0 (0%)	1 (10.0%)
Hypertonia	1 (16.7%)	0 (0%)	0 (0%)	0 (0%)	1 (10.0%)
Weight increased	0 (0%)	0 (0%)	0 (0%)	1 (25.0%)	1 (10.0%)

Part X - PTs not indicating ADR

PT not indicating ADR	ALEMTUZUMAB (N=89)	GLATIRAMER (N=292)	NATALIZUMAB (N=844)	OCRELIZUMAB (N=101)	Overall (N=1,326)
Adverse drug reaction	1 (1.1%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Adverse event	1 (1.1%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Drug exposure before pregnancy	20 (22.5%)	1 (0.3%)	0 (0%)	0 (0%)	21 (1.6%)
Drug monitoring procedure not performed	1 (1.1%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Exposure during pregnancy	28 (31.5%)	9 (3.1%)	3 (0.4%)	2 (2.0%)	42 (3.2%)
Exposure via breast milk	3 (3.4%)	6 (2.1%)	21 (2.5%)	2 (2.0%)	32 (2.4%)
Foetal exposure during pregnancy	7 (7.9%)	37 (12.7%)	179 (21.2%)	22 (21.8%)	245 (18.5%)
Foetal exposure timing unspecified	4 (4.5%)	0 (0%)	2 (0.2%)	0 (0%)	6 (0.5%)
Incorrect drug administration rate	1 (1.1%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Intentional product use issue	1 (1.1%)	0 (0%)	2 (0.2%)	1 (1.0%)	4 (0.3%)
Maternal exposure before pregnancy	2 (2.2%)	3 (1.0%)	0 (0%)	20 (19.8%)	25 (1.9%)
Maternal exposure during pregnancy	4 (4.5%)	134 (45.9%)	588 (69.7%)	35 (34.7%)	761 (57.4%)
Normal newborn	1 (1.1%)	39 (13.4%)	0 (0%)	0 (0%)	40 (3.0%)
Poor venous access	1 (1.1%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Pregnancy	14 (15.7%)	11 (3.8%)	2 (0.2%)	4 (4.0%)	31 (2.3%)
Accidental exposure to product	0 (0%)	1 (0.3%)	0 (0%)	0 (0%)	1 (0.1%)
Foetal monitoring	0 (0%)	1 (0.3%)	0 (0%)	0 (0%)	1 (0.1%)
Illness	0 (0%)	1 (0.3%)	0 (0%)	0 (0%)	1 (0.1%)
Inappropriate schedule of product administration	0 (0%)	1 (0.3%)	1 (0.1%)	0 (0%)	2 (0.2%)
Infant	0 (0%)	1 (0.3%)	0 (0%)	0 (0%)	1 (0.1%)
Intentional product misuse	0 (0%)	1 (0.3%)	0 (0%)	0 (0%)	1 (0.1%)
Live birth	0 (0%)	19 (6.5%)	0 (0%)	0 (0%)	19 (1.4%)
Maternal exposure during breast feeding	0 (0%)	20 (6.8%)	2 (0.2%)	1 (1.0%)	23 (1.7%)
Pregnancy test positive	0 (0%)	2 (0.7%)	0 (0%)	0 (0%)	2 (0.2%)

Product use in unapproved indication	0 (0%)	1 (0.3%)	1 (0.1%)	0 (0%)	2 (0.2%)
Therapy interrupted	0 (0%)	1 (0.3%)	0 (0%)	0 (0%)	1 (0.1%)
Wrong technique in product usage process	0 (0%)	3 (1.0%)	0 (0%)	0 (0%)	3 (0.2%)
Off label use	0 (0%)	0 (0%)	3 (0.4%)	4 (4.0%)	7 (0.5%)
Prescribed underdose	0 (0%)	0 (0%)	38 (4.5%)	0 (0%)	38 (2.9%)
Product dose omission issue	0 (0%)	0 (0%)	1 (0.1%)	0 (0%)	1 (0.1%)
Road traffic accident	0 (0%)	0 (0%)	1 (0.1%)	0 (0%)	1 (0.1%)
Drug interaction	0 (0%)	0 (0%)	0 (0%)	1 (1.0%)	1 (0.1%)
Maternal exposure timing unspecified	0 (0%)	0 (0%)	0 (0%)	8 (7.9%)	8 (0.6%)
Product storage error	0 (0%)	0 (0%)	0 (0%)	1 (1.0%)	1 (0.1%)