			Case Group	Death Outcomes	Sole
Case Count			121	3	57
Reaction	Blood and lymphatic system disorders	Anaemia	1	0	0
Count		Pancytopenia	1	1	1
		Haemolytic anaemia	1	0	0
		Coombs positive haemolytic anaemia	1	0	0
		Thrombocytopenia	2	1	1
		Leukocytosis	1	0	0
		Neutropenia	4	0	0
		Blood and lymphatic system disorders	11	2	2
	Cardiac disorders	Atrioventricular block	1	0	0
		Tachycardia	4	0	3
		Atrial fibrillation	1	0	0
		Supraventricular tachycardia	1	0	1
		Palpitations	1	0	1
		Cardiomyopathy	1	0	0
		Cardiac disorders	9	0	5
	Congenital, familial and genetic disorders	Multiple congenital abnormalities	1	0	0
		Anal atresia	1	0	0
		Oesophageal atresia	1	0	0
		Syndactyly	1	0	0
		Talipes	1	0	0
		Congenital musculoskeletal anomaly	1	0	0
		Congenital, familial and genetic disorders	6	0	0
	Ear and labyrinth disorders	Tinnitus	4	0	2
		Vertigo	2	0	1
		Ear and labyrinth disorders	6	0	3
	Eye disorders	Periorbital oedema	1	0	0
		Visual impairment	2	0	0
		Scotoma	1	0	0
		Eye disorders	4	0	0
	Gastrointestinal disorders	Anal pruritus	1	0	1
		Gingival hyperplasia	1	0	0
		Gingival bleeding	1	0	1
		Diarrhoea	1	0	1
		Constipation	1	0	1
		Ileus paralytic	1	0	0
		Abdominal pain	3	0	2
		Breath odour	1	0	1
		Dysphagia	1	0	1
		Nausea	6	0	1
		Vomiting	6	0	4
		Lip swelling	1	0	0

			Case Group	Death Outcomes	Sole
Reaction Count	Gastrointestinal disorders	Mouth ulceration	2	0	1
		Stomatitis	1	0	0
		Dry mouth	8	0	6
		Tongue oedema	1	0	0
		Gastrointestinal disorders	36	0	20
	General disorders and administration site conditions	Hyperpyrexia	1	1	1
		Pyrexia	2	0	0
		Sudden death	1	1	1
		Asthenia	1	0	0
		Fatigue	1	0	0
		Malaise	2	0	0
		Face oedema	1	0	1
		Generalised oedema	1	0	1
		Chills	1	0	0
		General disorders and administration site conditions	11	2	4
	Hepatobiliary disorders	Jaundice	2	0	1
		Hepatic function abnormal	4	0	1
		Hepatic steatosis	1	1	0
		Hepatobiliary disorders	7	1	2
	Infections and infestations	Vaginal infection	1	0	0
		Pharyngitis	1	0	1
		Infections and infestations	2	0	1
	Injury, poisoning and procedural complications	Fall	1	0	0
		Overdose	1	1	0
		Injury, poisoning and procedural complications	2	1	0
	Investigations	Weight increased	2	0	1
		Urine analysis abnormal	1	0	1
		Drug level increased	3	0	0
		Investigations	6	0	2
	Metabolism and nutrition disorders	Decreased appetite	2	0	0
		Metabolism and nutrition disorders	2	0	0
	Musculoskeletal and connective tissue disorders	Muscle twitching	2	0	1
		Musculoskeletal and connective tissue disorders	2	0	1
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acute leukaemia	2	0	0
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0	0
	Nervous system disorders	Encephalopathy	1	0	0
		Headache	2	0	0
		Akathisia	1	0	0
		Dyskinesia	2	0	0
		Extrapyramidal disorder	1	0	0

			Case Group	Death Outcomes	Sole
Reaction Count	Nervous system disorders	Dystonia	1	0	0
		Paresis	2	0	2
		Tremor	6	0	6
		Ataxia	2	0	0
		Somnolence	4	0	3
		Syncope	5	0	3
		Dizziness	10	0	7
		Paraesthesia	1	0	1
		Dysgeusia	2	0	1
		Speech disorder	1	0	1
		Serotonin syndrome	2	0	0
		Grand mal convulsion	4	0	3
		Convulsion	4	0	3
		Nervous system disorders	51	0	30
	Pregnancy, puerperium and perinatal	Premature baby	1	0	0
	conditions	Pregnancy, puerperium and perinatal conditions	1	0	0
	Psychiatric disorders	Agitation	5	0	1
		Anxiety	4	0	0
		Nervousness	1	0	1
		Neurosis	1	0	0
		Attention deficit/hyperactivity disorder	1	0	1
		Confusional state	9	0	6
		Disorientation	1	0	1
		Delirium	2	0	1
		Depersonalisation	1	0	0
		Dissociation	1	0	0
		Hallucination	5	0	1
		Affect lability	1	0	1
		Paranoia	2	0	0
		Insomnia	1	0	1
		Nightmare	3	0	3
		Suicide attempt	2	0	0
		Psychiatric disorders	40	0	17
	Renal and urinary disorders	Renal impairment	2	0	0
		Urinary retention	3	0	2
		Haematuria	1	1	1
		Renal and urinary disorders	6	1	3
	Reproductive system and breast disorders	Gynaecomastia	1	0	0
		Ejaculation failure	1	0	1
		Reproductive system and breast disorders	2	0	1
	Respiratory, thoracic and mediastinal disorders	Pulmonary oedema	1	1	0

			Case Group	Death Outcomes	Sole
Reaction Count	Respiratory, thoracic and mediastinal disorders	Infantile apnoeic attack	1	0	0
		Dyspnoea	1	0	1
		Hyperventilation	1	0	0
		Cough	2	0	0
		Dysphonia	1	0	1
		Respiratory, thoracic and mediastinal disorders	7	1	2
	Skin and subcutaneous tissue disorders	Dermatitis bullous	2	0	0
		Rash erythematous	1	0	1
		Photosensitivity reaction	3	0	1
		Pruritus	4	0	2
		Rash	3	1	3
		Rash maculo-papular	2	0	2
		Hyperhidrosis	1	0	1
		Nail disorder	1	0	1
		Purpura	2	1	1
		Skin and subcutaneous tissue disorders	19	2	12
	Surgical and medical procedures	Therapy regimen changed	1	0	1
		Surgical and medical procedures	1	0	1
	Vascular disorders	Peripheral ischaemia	1	0	0
		Circulatory collapse	1	0	1
		Hypotension	5	0	3
		Orthostatic hypotension	3	0	1
		Flushing	1	0	1
		Hot flush	1	0	0
		Hypertension	1	0	0
		Vascular disorders	13	0	6
	Reaction		246	10	112