			Case Group	Death Outcomes	Sole
Case Count			226	3	162
Reaction	Blood and lymphatic system disorders	Coagulopathy	1	0	1
Count		Thrombocytopenia	1	0	1
		Blood and lymphatic system disorders	2	0	2
	Cardiac disorders	Bradycardia	1	1	1
		Tachycardia	4	0	2
		Sinus bradycardia	1	0	1
		Cardiovascular insufficiency	1	0	0
		Palpitations	2	0	2
		Mitral valve incompetence	1	0	0
		Cardiac failure congestive	1	1	1
		Cardiac disorders	11	2	7
	Congenital, familial and genetic disorders	Ventricular septal defect	1	0	0
		Congenital, familial and genetic disorders	1	0	0
	Ear and labyrinth disorders	Deafness	1	0	1
		Hyperacusis	2	0	2
		Tinnitus	1	0	1
		Vertigo	1	0	1
		Ear and labyrinth disorders	5	0	5
	Endocrine disorders	Hyperprolactinaemia	2	0	2
		Inappropriate antidiuretic hormone secretion	1	0	1
		Endocrine disorders	3	0	3
	Eye disorders	Eye movement disorder	1	0	1
		Pupil fixed	1	0	1
		Photophobia	2	0	1
		Vision blurred	4	0	3
		Visual impairment	3	0	1
		Eye disorders	11	0	7
	Gastrointestinal disorders	Gastrointestinal haemorrhage	1	0	0
		Haematemesis	1	0	0
		Melaena	2	0	0
		Diarrhoea	9	0	8
		Constipation	2	1	0
		Bowel movement irregularity	1	0	1
		Dyspepsia	1	0	1
		Faeces discoloured	1	0	1
		Abdominal pain	3	0	2
		Abdominal pain upper	3	0	3
		Abdominal discomfort	3	0	3
		Dysphagia	3	0	1
		Nausea	28	0	21
		Retching	2	0	2

			Case Group	Death Outcomes	Sole
Reaction Count	Gastrointestinal disorders	Vomiting	4	0	3
		Duodenal ulcer	1	0	0
		Gastric ulcer haemorrhage	1	0	0
		Intestinal perforation	1	1	0
		Gastrointestinal necrosis	1	1	0
		Paraesthesia oral	1	0	1
		Dry mouth	3	0	3
		Tongue disorder	2	0	2
		Swollen tongue	1	0	1
		Gastrointestinal disorders	75	3	53
	General disorders and administration site	Temperature regulation disorder	1	0	1
	conditions	Pyrexia	6	0	3
		Asthenia	2	0	1
		Fatigue	2	0	2
		Malaise	4	0	3
		Abasia	1	0	0
		Gait disturbance	2	0	1
		Condition aggravated	1	0	0
		Influenza like illness	1	0	0
		Irritability	3	0	1
		Secretion discharge	1	0	1
		Oedema peripheral	2	0	2
		Chest pain	2	0	2
		Chills	4	0	2
		Feeling abnormal	1	0	1
		Feeling cold	1	0	1
		Feeling hot	2	0	1
		Feeling jittery	1	0	1
		Feeling of body temperature change	3	0	3
		Sensation of foreign body	1	0	1
		Thirst	3	0	2
		Drug interaction	2	0	0
		Drug ineffective	3	0	2
		Therapeutic response unexpected with drug substitution	6	0	6
		Drug withdrawal syndrome	4	0	4
		Drug withdrawal syndrome neonatal	1	0	1
		General disorders and administration site conditions	60	0	42
	Hepatobiliary disorders	Jaundice	2	0	0
		Hepatic function abnormal	1	0	0
		Hepatitis	3	0	0

			Case Group	Death Outcomes	Sole
Reaction	Hepatobiliary disorders	Hepatobiliary disorders	6	0	0
Count	Immune system disorders	Anaphylactic reaction	1	0	1
		Immune system disorders	1	0	1
	Infections and infestations	Pneumonia	1	1	0
		Sepsis	1	1	0
		Furuncle	1	0	1
		Rash pustular	1	0	1
		Infections and infestations	4	2	2
	Injury, poisoning and procedural	Drug exposure during pregnancy	2	0	1
	complications	Fall	6	0	3
		Contusion	4	0	3
		Drug prescribing error	1	0	0
		Overdose	3	0	0
		Injury, poisoning and procedural complications	16	0	7
	Investigations	Electrocardiogram QT prolonged	1	0	0
		Heart rate increased	1	0	1
		Blood pressure increased	2	0	2
		Blood creatine phosphokinase increased	5	0	2
		Bleeding time prolonged	1	0	1
		Liver function test abnormal	4	0	2
		Antinuclear antibody positive	1	0	1
		Blood glucose increased	1	0	1
		Body temperature fluctuation	1	0	1
		Weight decreased	2	0	2
		Weight increased	2	0	2
		Urine output decreased	1	0	1
		Investigations	22	0	16
	Metabolism and nutrition disorders	Decreased appetite	6	0	4
		Hypophagia	1	0	0
		Feeding disorder neonatal	1	0	1
		Hypokalaemia	1	0	1
		Hyponatraemia	17	0	11
		Hyperglycaemia	2	0	1
		Hypoglycaemia	1	0	1
		Hypoglycaemia neonatal	1	0	1
		Metabolism and nutrition disorders	30	0	20
	Musculoskeletal and connective tissue	Arthritis	1	0	1
	disorders	Polyarthritis	1	0	1
		Arthralgia	5	0	4
		Joint swelling	2	0	1
		Myalgia	5	0	2

			Case Group	Death Outcomes	Sole
Reaction Count	Musculoskeletal and connective tissue	Muscle spasms	1	0	1
	disorders	Muscle twitching	2	0	2
		Muscle rigidity	1	0	0
		Trismus	2	0	2
		Muscular weakness	2	0	0
		Myopathy	1	0	0
		Mobility decreased	1	0	0
		Musculoskeletal stiffness	2	0	0
		Back pain	2	0	2
		Musculoskeletal pain	1	0	0
		Musculoskeletal and connective tissue disorders	29	0	16
	Nervous system disorders	Cerebral haemorrhage	1	0	0
		Cerebrovascular accident	1	0	0
		Headache	9	0	6
		Migraine	3	0	2
		Amnesia	1	0	0
		Cognitive disorder	1	0	1
		Disturbance in attention	2	0	2
		Akathisia	4	0	3
		Dyskinesia	2	0	1
		Extrapyramidal disorder	1	0	0
		Psychomotor hyperactivity	1	0	1
		Tardive dyskinesia	1	0	1
		Dystonia	2	0	1
		Opisthotonus	1	0	0
		Cogwheel rigidity	2	0	0
		Tremor	10	0	6
		Ataxia	1	0	0
		Coordination abnormal	2	0	2
		Aphasia	1	0	1
		Depressed level of consciousness	1	0	0
		Lethargy	6	0	4
		Loss of consciousness	1	0	0
		Sedation	1	0	1
		Somnolence	2	0	1
		Syncope	3	0	3
		Dizziness	6	0	
		Dizziness postural	1	0	
		Drooling	1	0	
		Crying	1	0	1
		Hyperaesthesia	2	0	

			Case Group	Death Outcomes	Sole
Reaction Count	Nervous system disorders	Paraesthesia	5	0	4
		Dysgeusia	3	0	3
		Hypoaesthesia	2	0	1
		Restless legs syndrome	1	0	1
		Sensory disturbance	1	0	1
		Speech disorder	1	0	1
		Neuroleptic malignant syndrome	3	0	1
		Serotonin syndrome	12	0	6
		Petit mal epilepsy	1	0	0
		Grand mal convulsion	3	0	1
		Convulsion	7	0	5
		Drug withdrawal convulsions	1	0	1
		Epilepsy	1	0	0
		Nervous system disorders	112	0	68
	Pregnancy, puerperium and perinatal	Hypothermia neonatal	1	0	1
	conditions	Pregnancy, puerperium and perinatal conditions	1	0	1
	Psychiatric disorders	Agitation	15	0	10
		Agitation neonatal	1	0	1
		Anxiety	14	1	9
		Nervousness	2	0	1
		Tension	1	0	0
		Panic attack	4	0	3
		Panic reaction	3	0	3
		Restlessness	2	0	1
		Bruxism	1	0	1
		Tic	1	0	0
		Screaming	2	0	2
		Confusional state	9	0	6
		Disorientation	2	0	2
		Delirium	1	0	0
		Depression	13	1	9
		Depressed mood	1	0	1
		Tearfulness	1	0	1
		Depersonalisation	1	0	1
		Derealisation	1	0	1
		Hallucination	6	0	5
		Hallucination, visual	2	0	2
		Thinking abnormal	2	0	1
		Impulsive behaviour	1	0	1
		Onychophagia	1	0	1
		Pathological gambling	1	0	

			Case Group	Death Outcomes	Sole
Reaction	Psychiatric disorders	Mania	2	0	2
Count		Inappropriate affect	1	0	1
		Anger	3	0	2
		Elevated mood	1	0	1
		Emotional distress	1	0	1
		Euphoric mood	2	0	2
		Mood swings	3	0	3
		Apathy	1	0	1
		Aggression	3	0	3
		Antisocial behaviour	1	0	1
		Homicidal ideation	1	0	0
		Paranoia	1	0	1
		Abnormal behaviour	1	0	1
		Staring	1	0	0
		Mental disorder	1	0	0
		Withdrawal syndrome	1	0	1
		Acute psychosis	1	0	1
		Psychotic disorder	2	0	2
		Disturbance in sexual arousal	1	0	1
		Libido decreased	2	0	2
		Libido increased	1	0	1
		Loss of libido	1	0	0
		Insomnia	8	0	8
		Abnormal dreams	2	0	2
		Nightmare	7	0	4
		Sleep disorder	3	0	3
		Self-injurious ideation	3	0	3
		Suicidal behaviour	1	0	0
		Suicidal ideation	7	0	5
		Suicide attempt	3	0	2
		Psychiatric disorders	154	2	117
	Renal and urinary disorders	Tubulointerstitial nephritis	1	0	1
		Renal failure acute	2	0	2
		Dysuria	2	0	2
		Urinary hesitation	1	0	1
		Urinary incontinence	1	0	1
		Urinary retention	2	0	1
		Chromaturia	2	0	0
		Renal and urinary disorders	11	0	8
	Reproductive system and breast disorders	Gynaecomastia	1	0	1
		Galactorrhoea	2	0	2
		Menopausal symptoms	1	0	1

			Case Group	Death Outcomes	Sole
Reaction	Reproductive system and breast disorders	Dysfunctional uterine bleeding	1	0	1
Count		Ejaculation disorder	1	0	1
		Ejaculation failure	1	0	1
		Sexual dysfunction	1	0	1
		Reproductive system and breast disorders	8	0	8
	Respiratory, thoracic and mediastinal	Bronchospasm	1	0	1
	disorders	Obstructive airways disorder	1	0	0
		Wheezing	1	0	1
		Neonatal respiratory distress syndrome	1	0	1
		Pulmonary embolism	1	0	0
		Dyspnoea	1	0	1
		Cough	1	0	1
		Throat tightness	1	0	1
		Yawning	1	0	1
		Laryngospasm	1	0	0
		Sinus congestion	2	0	2
		Pharyngeal oedema	1	0	1
		Respiratory, thoracic and mediastinal disorders	13	0	10
	Skin and subcutaneous tissue disorders	Angioedema	1	0	0
		Urticaria	5	0	5
		Skin burning sensation	1	0	1
		Skin disorder	1	0	0
		Skin reaction	1	0	1
		Swelling face	1	0	1
		Rash erythematous	3	0	2
		Lichen sclerosus	1	0	0
		Rash papular	1	0	0
		Pruritus	4	0	3
		Pruritus generalised	1	0	1
		Rash pruritic	2	0	2
		Psoriasis	1	0	1
		Acute generalised exanthematous pustulosis	1	0	0
		Rash	11	0	8
		Erythema nodosum	1	0	1
		Alopecia	3	0	3
		Cold sweat	2	0	2
		Hyperhidrosis	12	0	7
		Night sweats	1	0	1
		Ecchymosis	2	0	2
		Petechiae	1	0	1
		Skin and subcutaneous tissue disorders	57	0	

			Case Group	Death Outcomes	Sole
Reaction	Surgical and medical procedures	Therapy regimen changed	6	0	2
Count		Surgical and medical procedures	6	0	2
	Vascular disorders	Peripheral ischaemia	1	0	0
		Circulatory collapse	3	0	0
		Hypotension	3	1	2
		Orthostatic hypotension	2	0	2
		Embolism venous	1	0	0
		Deep vein thrombosis	1	1	1
		Flushing	2	0	1
		Hot flush	2	0	1
		Haemorrhage	2	0	1
		Hypertension	2	0	1
		Vascular disorders	19	2	9
	Reaction		657	11	446