			Case Group	Death Outcomes	Sole
Case Count			83	0	67
Reaction	Blood and lymphatic system disorders	Platelet disorder	1	0	1
Count		Thrombocytopenia	1	0	1
		Blood and lymphatic system disorders	2	0	2
	Cardiac disorders	Bradycardia	1	0	1
		Tachycardia	2	0	2
		Palpitations	2	0	2
		Cardiac disorders	5	0	5
	Congenital, familial and genetic disorders	Cardiac septal defect	1	0	1
		Congenital anomaly	1	0	1
		Hernia congenital	1	0	0
		Cleft palate	1	0	1
		Dysmorphism	1	0	1
		Congenital, familial and genetic disorders	5	0	4
	Eye disorders	Eye rolling	1	0	0
		Diplopia	1	0	1
		Eye disorders	2	0	1
	Gastrointestinal disorders	Flatulence	1	0	1
		Abdominal pain	3	0	3
		Faecal incontinence	1	0	1
		Nausea	3	0	3
		Gastrointestinal disorders	8	0	8
	General disorders and administration site conditions	Pyrexia	2	0	2
		Developmental delay	2	0	2
		Face oedema	1	0	1
		Feeling jittery	2	0	1
		Drug ineffective	2	0	1
		Drug withdrawal syndrome neonatal	3	0	3
		General disorders and administration site conditions	12	0	10
	Infections and infestations	Candidiasis	2	0	0
		Infections and infestations	2	0	0
	Injury, poisoning and procedural	Drug exposure during pregnancy	9	0	7
	complications	Contusion	1	0	1
		Medication error	1	0	1
		Drug exposure via breast milk	1	0	1
		Accidental overdose	1	0	1
		Injury, poisoning and procedural complications	13	0	11
	Investigations	Apgar score low	1	0	1
		Body temperature decreased	1	0	1
		Weight increased	1	0	1

			Case Group	Death Outcomes	Sole
Reaction	Investigations	Investigations	3	0	3
Count	Metabolism and nutrition disorders	Decreased appetite	1	0	1
		Increased appetite	1	0	1
		Feeding disorder neonatal	1	0	1
		Metabolism and nutrition disorders	3	0	3
	Musculoskeletal and connective tissue disorders	Muscle spasms	1	0	1
		Muscle twitching	1	0	1
		Muscle rigidity	1	0	1
		Musculoskeletal and connective tissue disorders	3	0	3
	Nervous system disorders	Haemorrhage intracranial	1	0	1
		Hypoxic encephalopathy	1	0	1
		Headache	3	0	2
		Autism	2	0	2
		Dyskinesia	1	0	0
		Hyperkinesia	1	0	1
		Dystonia	1	0	1
		Opisthotonus	2	0	1
		Myoclonus	1	0	1
		Paraesthesia	1	0	1
		Hypotonia	1	0	1
		Serotonin syndrome	1	0	0
		Convulsion neonatal	1	0	0
		Convulsion	5	0	4
		Tonic convulsion	1	0	1
		Nervous system disorders	23	0	17
	Pregnancy, puerperium and perinatal conditions	Foetal malpresentation	1	0	1
		Premature baby	1	0	1
		Umbilical cord prolapse	1	0	1
		Pregnancy, puerperium and perinatal conditions	3	0	3
	Psychiatric disorders	Agitation	3	0	3
		Agitation neonatal	3	0	3
		Anxiety	3	0	3
		Nervousness	1	0	1
		Panic attack	1	0	1
		Neurosis	1	0	1
		Obsessive-compulsive disorder	1	0	0
		Bruxism	1	0	1
		Learning disorder	1	0	1
		Delirium	1	0	1
		Depression	1	0	1

			Case Group	Death Outcomes	Sole
Reaction Count	Psychiatric disorders	Depersonalisation	1	0	1
		Hallucination	1	0	1
		Hallucination, auditory	1	0	1
		Mania	2	0	2
		Affect lability	3	0	3
		Apathy	1	0	0
		Aggression	7	0	7
		Personality disorder	4	0	4
		Withdrawal syndrome	3	0	2
		Insomnia	2	0	2
		Nightmare	2	0	2
		Self injurious behaviour	1	0	0
		Suicidal ideation	1	0	0
		Psychiatric disorders	46	0	41
	Renal and urinary disorders	Tubulointerstitial nephritis	1	0	1
		Renal failure	1	0	1
		Renal tubular necrosis	1	0	1
		Urinary incontinence	1	0	1
		Renal and urinary disorders	4	0	4
	Reproductive system and breast disorders	Breast mass	1	0	0
		Reproductive system and breast disorders	1	0	0
	Respiratory, thoracic and mediastinal disorders	Neonatal asphyxia	1	0	1
		Neonatal respiratory depression	1	0	1
		Neonatal respiratory distress syndrome	2	0	2
		Pulmonary hypertension	1	0	0
		Apnoea	2	0	2
		Epistaxis	1	0	1
		Respiratory, thoracic and mediastinal disorders	8	0	7
	Skin and subcutaneous tissue disorders	Urticaria	2	0	2
		Skin discolouration	1	0	1
		Pruritus	4	0	4
		Rash pruritic	1	0	1
		Rash macular	1	0	0
		Rash maculo-papular	2	0	2
		Alopecia	2	0	1
		Hyperhidrosis	1	0	1
		Purpura	1	0	1
		Skin and subcutaneous tissue disorders	15	0	13
	Surgical and medical procedures	Therapy regimen changed	1	0	1
		Surgical and medical procedures	1	0	1
	Vascular disorders	Flushing	1	0	0

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			Case Group	Death Outcomes	Sole
Reaction Count	Vascular disorders	Hypertension	1	0	0
		Vascular disorders	2	0	0
	Reaction		161	0	136