

Summary Tabulation 22-06-2021

Active Substance (High Level)		COVID-19 MRNA VACCINE MODERNA (CX-024414)		
Reaction SOC	Reaction PT	Serious	Non Serious	Total
Blood and lymphatic system disorders	Coagulopathy	2	1	3
	Lymph node pain	0	1	1
	Lymphadenitis	1	0	1
	Lymphadenopathy	7	1	8
	Thrombocytopenia	2	0	2
Cardiac disorders	Arrhythmia	1	0	1
	Atrial fibrillation	1	0	1
	Bradycardia	1	0	1
	Cardiac arrest	1	0	1
	Cardiac failure	2	0	2
	Cardiovascular disorder	14	2	16
	Coronary artery occlusion	1	0	1
	Extrasystoles	1	0	1
	Palpitations	5	2	7
	Pericarditis	2	0	2
	Tachycardia	5	3	8
Ear and labyrinth disorders	Deafness	1	0	1
	Ear discomfort	1	0	1
	Ear pain	1	0	1
	Hyperacusis	2	0	2
	Tinnitus	7	0	7
	Vertigo	4	1	5
Endocrine disorders	Hypothyroidism	1	0	1
Eye disorders	Conjunctival haemorrhage	1	0	1
	Diplopia	0	1	1
	Eye oedema	0	1	1
	Eye pain	2	0	2
	Iridocyclitis	0	1	1
	Lacrimation increased	0	1	1
	Photophobia	1	0	1
	Scleritis	1	0	1
	Swelling of eyelid	0	1	1
	Vision blurred	2	0	2
	Visual impairment	2	1	3
Gastrointestinal disorders	Abdominal discomfort	0	1	1

Abdominal pain	7	2	9
Abdominal pain upper	2	1	3
Aphthous ulcer	1	0	1
Diarrhoea	11	4	15
Dyspepsia	1	0	1
Haematochezia	1	0	1
Hypoaesthesia oral	0	1	1
Lip swelling	3	1	4
Nausea	112	21	133
Paraesthesia oral	1	1	2
Retching	0	1	1
Swollen tongue	1	0	1
Vomiting	19	4	23
General disorders and administration site conditions			
Adverse reaction	0	1	1
Asthenia	11	4	15
Axillary pain	0	3	3
Chest discomfort	2	1	3
Chest pain	4	1	5
Chills	176	33	209
Cyst	0	1	1
Death	5	0	5
Discomfort	2	0	2
Extensive swelling of vaccinated limb	37	7	44
Face oedema	0	1	1
Fatigue	203	41	244
Feeling abnormal	1	1	2
Feeling cold	2	1	3
Feeling hot	5	1	6
Feeling of body temperature change	3	0	3
Gait disturbance	3	0	3
Hyperthermia	0	1	1
Hypothermia	1	0	1
Inflammation	1	0	1
Inflammatory pain	1	0	1
Influenza like illness	24	4	28
Injected limb mobility decreased	1	0	1
Injection site erythema	6	13	19
Injection site haematoma	2	0	2
Injection site hypersensitivity	0	1	1
Injection site induration	2	5	7
Injection site movement impairment	1	0	1
Injection site oedema	1	0	1
Injection site pain	12	12	24
Injection site paraesthesia	1	0	1
Injection site pruritus	0	3	3
Injection site reaction	154	31	185
Injection site swelling	5	5	10
Injection site warmth	1	0	1
Malaise	113	23	136
Oedema peripheral	1	0	1

	Pain	5	0	5
	Peripheral swelling	16	6	22
	Pyrexia	219	47	266
	Sudden death	1	0	1
	Swelling face	2	1	3
	Vaccination failure	1	0	1
	Vaccination site erythema	1	1	2
	Vaccination site lymphadenopathy	0	1	1
	Vaccination site mass	1	1	2
	Vaccination site movement impairment	2	0	2
	Vaccination site pain	2	1	3
	Vaccination site swelling	1	0	1
Hepatobiliary disorders	Liver disorder	1	0	1
Immune system disorders	Allergy to vaccine	1	0	1
	Anaphylactic reaction	3	0	3
	Anaphylactic shock	1	0	1
	Autoimmune disorder	0	1	1
	Hypersensitivity	5	1	6
	Immune system disorder	0	1	1
Infections and infestations	COVID-19	15	0	15
	COVID-19 pneumonia	1	0	1
	Cellulitis	1	0	1
	Erysipelas	1	0	1
	Herpes zoster	4	9	13
	Influenza	2	0	2
	Nasopharyngitis	1	0	1
	Peritonsillar abscess	1	0	1
	Pneumonia	2	0	2
	Vaccination site joint infection	1	0	1
Injury, poisoning and procedural complications	Contusion	0	2	2
	Exposure via breast milk	1	0	1
	Fall	1	1	2
	Off label use	0	1	1
	Product dose omission issue	1	0	1
Investigations	Blood pressure decreased	2	0	2
	Body temperature abnormal	1	0	1
	Body temperature increased	0	1	1
	C-reactive protein increased	0	1	1
	Fibrin D dimer increased	1	0	1
	Heart rate increased	3	1	4
	Heart rate irregular	0	1	1
	Liver function test abnormal	1	0	1
	Oxygen saturation decreased	3	1	4
	Platelet count decreased	1	0	1
	Weight increased	2	0	2
Metabolism and nutrition disorders	Decreased appetite	12	1	13
Musculoskeletal and connective tissue disorders	Arthralgia	119	14	133
	Back pain	1	2	3
	Joint swelling	0	1	1
	Limb discomfort	1	0	1

Muscle rigidity	2	0	2
Muscle spasms	0	1	1
Muscular weakness	5	1	6
Musculoskeletal discomfort	1	0	1
Musculoskeletal stiffness	4	2	6
Myalgia	186	50	236
Neck pain	2	2	4
Pain in extremity	10	10	20
Pain in jaw	1	0	1
Nervous system disorders			
Ageusia	2	0	2
Altered state of consciousness	1	0	1
Anosmia	1	0	1
Balance disorder	2	0	2
Bell's palsy	0	1	1
Burning sensation	0	2	2
Cerebral artery thrombosis	1	0	1
Cerebral thrombosis	1	0	1
Cerebrovascular accident	2	0	2
Dizziness	24	3	27
Dysarthria	1	0	1
Dysgeusia	2	0	2
Dystonia	1	0	1
Facial paralysis	1	3	4
Haemorrhagic transformation stroke	1	0	1
Head discomfort	2	0	2
Headache	187	41	228
Hyperaesthesia	1	1	2
Hypoaesthesia	4	1	5
Hypokinesia	1	0	1
Hyporeflexia	1	0	1
Ischaemic stroke	1	0	1
Loss of consciousness	1	1	2
Migraine	5	1	6
Nervous system disorder	5	0	5
Paraesthesia	2	1	3
Paralysis	1	0	1
Paraplegia	1	0	1
Paresis	1	0	1
Parosmia	1	0	1
Post herpetic neuralgia	0	1	1
Presyncope	1	2	3
Seizure	0	1	1
Sensorimotor disorder	1	0	1
Sleep deficit	2	0	2
Somnolence	3	0	3
Spinal artery embolism	1	0	1
Syncope	5	3	8
Taste disorder	2	0	2
Tension headache	0	1	1
Transient ischaemic attack	1	0	1

	Tremor	1	0	1
Psychiatric disorders	Abnormal dreams	1	0	1
	Apathy	1	0	1
	Confusional state	0	1	1
	Insomnia	3	0	3
Renal and urinary disorders	Chromaturia	1	0	1
	Polyuria	1	0	1
	Renal disorder	1	0	1
	Strangury	1	0	1
Reproductive system and breast disorders	Breast engorgement	1	0	1
	Breast mass	1	0	1
	Breast pain	1	0	1
	Breast swelling	1	0	1
	Heavy menstrual bleeding	0	2	2
	Intermenstrual bleeding	0	1	1
	Menstrual disorder	1	0	1
Respiratory, thoracic and mediastinal disorders	Acute pulmonary oedema	1	0	1
	Apnoea	1	0	1
	Asphyxia	1	0	1
	Choking sensation	0	2	2
	Cough	5	1	6
	Dysphonia	1	0	1
	Dyspnoea	12	3	15
	Epistaxis	0	1	1
	Hypoxia	1	0	1
	Nocturnal dyspnoea	1	0	1
	Oropharyngeal pain	7	0	7
	Pharyngeal swelling	1	0	1
	Pulmonary embolism	2	0	2
	Pulmonary infarction	1	0	1
	Pulmonary pain	0	1	1
	Respiration abnormal	1	0	1
	Respiratory disorder	14	3	17
	Rhinalgia	1	0	1
	Rhinorrhoea	1	0	1
	Sputum discoloured	1	0	1
Wheezing	1	0	1	
Skin and subcutaneous tissue disorders	Angioedema	1	0	1
	Blister	0	1	1
	Cold sweat	1	0	1
	Cutaneous sarcoidosis	1	0	1
	Erythema	4	3	7
	Erythema nodosum	1	0	1
	Hyperhidrosis	7	1	8
	Petechiae	1	0	1
	Pruritus	5	1	6
	Psoriasis	0	1	1
	Rash	3	3	6
	Rash erythematous	1	0	1
	Rash maculo-papular	1	0	1

	Sensitive skin	0	1	1
	Skin disorder	16	19	35
	Urticaria	3	2	5
Vascular disorders	Blood pressure fluctuation	1	0	1
	Cyanosis	1	0	1
	Deep vein thrombosis	1	0	1
	Diastolic hypertension	1	0	1
	Flushing	1	0	1
	Haematoma	1	1	2
	Hot flush	1	0	1
	Hypertension	3	1	4
	Hypertensive crisis	1	0	1
	Hypotension	4	0	4
	Infarction	1	0	1
	Lymphoedema	1	0	1
	Pallor	2	2	4
	Thrombosis	1	2	3
	Vasculitis	1	0	1
Total		2068	527	2 595