

## Summary Tabulation 07-09-2021

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	7	1	8
	Lymph node pain	0	1	1
	Lymphadenitis	1	0	1
	Lymphadenopathy	31	5	36
	Splenic infarction	1	0	1
	Thrombocytopenia	5	0	5
Cardiac disorders	Acute myocardial infarction	2	0	2
	Angina pectoris	2	0	2
	Arrhythmia	4	1	5
	Atrial fibrillation	4	0	4
	Atrial flutter	1	0	1
	Bradycardia	1	0	1
	Cardiac arrest	3	0	3
	Cardiac discomfort	1	0	1
	Cardiac failure	2	0	2
	Cardiac tamponade	1	0	1
	Cardiovascular disorder	27	2	29
	Coronary artery occlusion	1	0	1
	Extrasystoles	3	0	3
	Heart alternation	1	0	1
	Myocardial ischaemia	1	0	1
	Myocarditis	4	0	4
	Palpitations	21	5	26
	Pericarditis	6	1	7
	Sinus bradycardia	1	0	1
	Supraventricular extrasystoles	1	0	1
	Tachycardia	8	8	16
Ventricular extrasystoles	1	0	1	
Congenital, familial and genetic disorders	Limb malformation	1	0	1
Ear and labyrinth disorders	Deafness	1	0	1
	Ear discomfort	5	1	6
	Ear pain	3	0	3
	Hyperacusis	4	1	5
	Inner ear disorder	0	1	1
	Tinnitus	9	3	12
	Vertigo	12	15	27
Endocrine disorders	Goitre	1	0	1
	Hypothyroidism	1	0	1

	Thyroiditis subacute	0	1	1
Eye disorders	Blindness	2	1	3
	Conjunctival haemorrhage	1	1	2
	Diplopia	2	1	3
	Dry eye	0	1	1
	Eye discharge	1	0	1
	Eye haemorrhage	1	0	1
	Eye oedema	0	1	1
	Eye pain	4	2	6
	Eye swelling	1	0	1
	Eyelid pain	0	1	1
	Eyelids pruritus	1	0	1
	Iridocyclitis	0	1	1
	Lacrimation increased	0	1	1
	Ocular discomfort	1	0	1
	Photophobia	4	1	5
	Retinal detachment	1	0	1
	Scleritis	1	0	1
	Swelling of eyelid	0	1	1
	Uveitis	0	1	1
	Vision blurred	6	0	6
	Visual impairment	4	5	9
	Gastrointestinal disorders	Abdominal discomfort	3	1
Abdominal distension		0	1	1
Abdominal pain		14	5	19
Abdominal pain lower		1	0	1
Abdominal pain upper		11	5	16
Abdominal rigidity		0	1	1
Aphthous ulcer		1	1	2
Constipation		1	0	1
Diarrhoea		28	9	37
Dry mouth		2	0	2
Dyspepsia		4	0	4
Dysphagia		2	0	2
Eructation		1	0	1
Gastrointestinal disorder		0	1	1
Gastrointestinal pain		1	0	1
Haematochezia		1	0	1
Haemorrhoids		1	0	1
Hypoaesthesia oral		0	1	1
Lip swelling		3	1	4
Mouth swelling		0	1	1
Nausea		377	88	465
Odynophagia		1	0	1
Oesophageal spasm		1	0	1
Paraesthesia oral		1	1	2
Retching		0	2	2
Swollen tongue		3	2	5
Toothache		2	0	2
Vomiting		59	16	75

General disorders and administration site conditions	Asthenia	28	10	38
	Axillary pain	6	12	18
	Chest discomfort	5	6	11
	Chest pain	14	7	21
	Chills	509	135	644
	Condition aggravated	2	1	3
	Cyst	0	1	1
	Death	8	0	8
	Decreased activity	1	0	1
	Discomfort	6	1	7
	Disease recurrence	1	0	1
	Extensive swelling of vaccinated limb	144	36	180
	Face oedema	1	1	2
	Fatigue	630	188	818
	Feeling abnormal	5	8	13
	Feeling cold	10	4	14
	Feeling hot	15	5	20
	Feeling of body temperature change	5	1	6
	Gait disturbance	7	0	7
	General physical health deterioration	1	0	1
	Hangover	3	0	3
	Hyperthermia	0	1	1
	Hypothermia	1	0	1
	Illness	2	0	2
	Induration	0	1	1
	Inflammation	1	1	2
	Inflammatory pain	1	0	1
	Influenza like illness	74	16	90
	Injected limb mobility decreased	1	0	1
	Injection site bruising	1	0	1
	Injection site dermatitis	1	0	1
	Injection site discomfort	1	0	1
	Injection site erythema	34	26	60
	Injection site haematoma	3	1	4
	Injection site hypersensitivity	1	2	3
	Injection site induration	7	7	14
	Injection site inflammation	2	2	4
	Injection site lymphadenopathy	1	0	1
	Injection site macule	0	1	1
	Injection site movement impairment	6	0	6
	Injection site necrosis	0	1	1
	Injection site oedema	1	0	1
Injection site pain	37	22	59	
Injection site paraesthesia	2	0	2	
Injection site plaque	2	1	3	
Injection site pruritus	7	4	11	
Injection site rash	2	0	2	
Injection site reaction	456	116	572	
Injection site swelling	20	18	38	
Injection site warmth	12	1	13	

	Malaise	431	88	519
	Mass	0	1	1
	Oedema peripheral	4	2	6
	Pain	21	10	31
	Peripheral swelling	28	13	41
	Pyrexia	588	160	748
	Sense of oppression	1	0	1
	Sensitivity to weather change	0	1	1
	Sudden death	1	0	1
	Swelling	1	2	3
	Swelling face	2	2	4
	Systemic inflammatory response	1	1	2
	Terminal state	1	0	1
	Thirst	3	1	4
	Vaccination failure	1	0	1
	Vaccination site bruising	0	1	1
	Vaccination site erythema	2	12	14
	Vaccination site lymphadenopathy	0	2	2
	Vaccination site mass	1	2	3
	Vaccination site movement impairment	2	2	4
	Vaccination site pain	6	14	20
	Vaccination site plaque	0	1	1
	Vaccination site pruritus	0	1	1
	Vaccination site reaction	0	1	1
	Vaccination site swelling	3	3	6
	Vaccination site warmth	0	3	3
Hepatobiliary disorders	Hepatitis	0	1	1
	Liver disorder	3	1	4
Immune system disorders	Allergy to vaccine	1	1	2
	Anaphylactic reaction	5	0	5
	Anaphylactic shock	4	1	5
	Autoimmune disorder	1	1	2
	Drug hypersensitivity	0	1	1
	Hypersensitivity	6	1	7
	Immune system disorder	0	1	1
Infections and infestations	Bronchitis	0	1	1
	COVID-19	20	2	22
	COVID-19 pneumonia	1	0	1
	Cellulitis	1	1	2
	Erysipelas	3	0	3
	Herpes virus infection	0	1	1
	Herpes zoster	8	24	32
	Herpes zoster meningoencephalitis	1	0	1
	Infection	0	1	1
	Influenza	4	0	4
	Localised infection	1	0	1
	Meningitis viral	1	0	1
	Mucosal infection	2	0	2
	Myelitis	1	0	1
	Nasopharyngitis	2	4	6

	Ophthalmic herpes zoster	1	0	1
	Oral herpes	1	0	1
	Peritonsillar abscess	1	0	1
	Pneumonia	3	0	3
	Sinusitis	1	0	1
	Skin infection	1	0	1
	Vaccination site joint infection	1	0	1
	Vaccination site pustule	0	1	1
	Viral infection	1	0	1
Injury, poisoning and procedural complications	Airway burns	1	0	1
	Cartilage injury	1	0	1
	Contusion	2	6	8
	Exposure via breast milk	1	1	2
	Fall	5	1	6
	Heat stroke	0	1	1
	Inappropriate schedule of product	0	31	31
	Incorrect dose administered	0	1	1
	Joint injury	1	0	1
	Musculoskeletal injury	1	0	1
	Off label use	0	1	1
	Product administered to patient of	0	1	1
	Product dose omission issue	2	3	5
	Tracheal injury	1	0	1
	Vaccination complication	1	5	6
	Wound	1	1	2
	Wrong technique in product usage	0	1	1
Investigations	Antibody test negative	0	1	1
	Arteriogram carotid abnormal	1	0	1
	Biopsy artery	1	0	1
	Blood fibrinogen increased	1	0	1
	Blood glucose increased	0	1	1
	Blood pressure decreased	4	3	7
	Blood pressure increased	1	3	4
	Blood prolactin decreased	1	0	1
	Body temperature abnormal	1	0	1
	Body temperature decreased	1	0	1
	Body temperature fluctuation	2	0	2
	Body temperature increased	2	1	3
	C-reactive protein increased	6	1	7
	Ejection fraction decreased	1	0	1
	Electrocardiogram ST segment	2	0	2
	Fibrin D dimer increased	4	0	4
	Heart rate decreased	1	0	1
	Heart rate increased	8	3	11
	Heart rate irregular	1	1	2
	Hormone level abnormal	0	1	1
	Liver function test abnormal	1	0	1
	Oxygen saturation decreased	3	1	4
	Platelet count decreased	1	0	1
	Red blood cell count decreased	1	0	1

	Red blood cell sedimentation rate	1	0	1
	SARS-CoV-2 test negative	2	0	2
	SARS-CoV-2 test positive	2	1	3
	Serum ferritin increased	1	0	1
	Troponin increased	4	0	4
	Weight decreased	3	1	4
	Weight increased	2	0	2
	White blood cell count decreased	1	0	1
Metabolism and nutrition disorders	Decreased appetite	27	6	33
	Dehydration	0	2	2
	Folate deficiency	1	0	1
	Vitamin B12 deficiency	1	0	1
Musculoskeletal and connective tissue disorders	Arthralgia	341	92	433
	Axillary mass	3	4	7
	Back pain	14	6	20
	Bone pain	2	0	2
	Groin pain	0	1	1
	Joint stiffness	1	0	1
	Joint swelling	2	2	4
	Limb discomfort	12	10	22
	Muscle fatigue	0	1	1
	Muscle rigidity	3	0	3
	Muscle spasms	3	4	7
	Muscular weakness	9	3	12
	Musculoskeletal chest pain	0	1	1
	Musculoskeletal discomfort	2	0	2
	Musculoskeletal stiffness	22	6	28
	Myalgia	563	177	740
	Neck pain	7	4	11
	Pain in extremity	53	30	83
	Pain in jaw	1	0	1
	Periarthritis	1	0	1
	Polymyalgia rheumatica	0	1	1
	Rheumatic disorder	1	0	1
	Torticollis	2	0	2
Nervous system disorders	Ageusia	5	2	7
	Altered state of consciousness	1	0	1
	Amnesia	0	1	1
	Anosmia	1	0	1
	Aphasia	1	1	2
	Balance disorder	4	3	7
	Bell's palsy	0	1	1
	Burning sensation	3	4	7
	Central pain syndrome	1	0	1
	Cerebral artery thrombosis	1	0	1
	Cerebral haemorrhage	1	0	1
	Cerebral thrombosis	1	0	1
	Cerebral venous sinus thrombosis	1	0	1
	Cerebrovascular accident	5	1	6
	Cognitive disorder	1	0	1

Coordination abnormal	2	0	2
Diplegia	1	0	1
Disturbance in attention	4	0	4
Dizziness	42	9	51
Dizziness postural	1	0	1
Dysarthria	1	0	1
Dysgeusia	2	0	2
Dysstasia	2	1	3
Dystonia	1	0	1
Electric shock sensation	0	1	1
Facial paralysis	4	4	8
Formication	1	0	1
Guillain-Barre syndrome	2	0	2
Haemorrhagic transformation stroke	1	0	1
Head discomfort	6	0	6
Headache	583	165	748
Hemianopia	0	1	1
Hemiparesis	1	0	1
Hemiplegia	2	0	2
Hyperaesthesia	1	1	2
Hypersomnia	0	1	1
Hypoaesthesia	9	7	16
Hypokinesia	1	0	1
Hyporeflexia	1	0	1
Intention tremor	1	0	1
Ischaemic stroke	1	0	1
Lethargy	1	0	1
Loss of consciousness	6	2	8
Memory impairment	2	0	2
Meningism	1	0	1
Migraine	16	5	21
Migraine with aura	1	0	1
Monoplegia	1	0	1
Motor dysfunction	1	0	1
Movement disorder	2	0	2
Muscle contractions involuntary	3	0	3
Nervous system disorder	13	2	15
Neuralgia	2	1	3
Neuropathy peripheral	0	1	1
Paraesthesia	13	10	23
Paralysis	1	0	1
Paraplegia	1	0	1
Paresis	1	0	1
Parosmia	2	0	2
Post herpetic neuralgia	0	2	2
Presyncope	5	3	8
Radiculopathy	1	0	1
Retinal migraine	0	1	1
Seizure	1	2	3
Sensorimotor disorder	1	0	1

	Sensory disturbance	1	0	1
	Sensory loss	1	0	1
	Sleep deficit	2	0	2
	Somnolence	7	2	9
	Speech disorder	0	1	1
	Spinal artery embolism	1	0	1
	Syncope	15	4	19
	Taste disorder	3	0	3
	Tension headache	0	1	1
	Transient ischaemic attack	1	0	1
	Tremor	6	2	8
	Trigeminal neuralgia	2	0	2
Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	3	1	4
	Morning sickness	1	0	1
	Premature baby	1	0	1
	Uterine hypertonus	1	0	1
Psychiatric disorders	Abnormal dreams	3	0	3
	Agoraphobia	1	0	1
	Anxiety	0	2	2
	Apathy	1	0	1
	Confusional state	3	1	4
	Delirium	1	0	1
	Depressed mood	0	1	1
	Disorientation	0	1	1
	Eating disorder	1	0	1
	Emotional disorder	1	1	2
	Fear	1	1	2
	Head banging	3	0	3
	Illusion	1	0	1
	Insomnia	16	5	21
	Mental disorder	1	0	1
	Mood altered	1	0	1
	Mood swings	1	0	1
	Nervousness	3	0	3
	Nightmare	2	0	2
	Panic reaction	1	0	1
	Poor quality sleep	2	1	3
	Restlessness	2	0	2
	Sleep disorder	5	1	6
	Sleep disorder due to general medical condition, hypersomnia type	0	1	1
Renal and urinary disorders	Chromaturia	1	0	1
	Dysuria	1	0	1
	Incontinence	0	1	1
	Pollakiuria	1	0	1
	Polyuria	1	0	1
	Renal disorder	2	1	3
	Renal pain	4	1	5
	Strangury	1	0	1
	Urinary incontinence	0	1	1
Reproductive system and breast disorders	Adnexa uteri pain	1	0	1



	Amenorrhoea	2	2	4
	Breast engorgement	1	0	1
	Breast mass	1	0	1
	Breast pain	4	1	5
	Breast swelling	1	1	2
	Cervix disorder	0	1	1
	Dysmenorrhoea	13	0	13
	Heavy menstrual bleeding	8	3	11
	Intermenstrual bleeding	1	1	2
	Menometrorrhagia	1	0	1
	Menstrual disorder	7	4	11
	Menstruation delayed	1	0	1
	Menstruation irregular	10	2	12
	Oligomenorrhoea	3	0	3
	Polymenorrhoea	8	0	8
	Uterine spasm	1	0	1
	Vulval disorder	0	1	1
	Vulvovaginal discomfort	1	0	1
Respiratory, thoracic and mediastinal disorders	Acute pulmonary oedema	1	0	1
	Aphonia	1	0	1
	Apnoea	1	0	1
	Asphyxia	1	0	1
	Choking sensation	0	2	2
	Cough	8	4	12
	Dry throat	1	0	1
	Dysphonia	2	0	2
	Dyspnoea	25	12	37
	Dyspnoea exertional	1	1	2
	Epistaxis	0	1	1
	Hypoxia	1	0	1
	Laryngeal oedema	1	0	1
	Nasal congestion	3	1	4
	Nasal discomfort	2	0	2
	Nocturnal dyspnoea	1	1	2
	Oropharyngeal pain	17	2	19
	Pharyngeal swelling	2	0	2
	Pleurisy	0	1	1
	Productive cough	1	1	2
	Pulmonary embolism	4	0	4
	Pulmonary infarction	1	0	1
	Pulmonary pain	2	1	3
	Respiration abnormal	1	0	1
	Respiratory depth decreased	1	0	1
	Respiratory disorder	18	5	23
	Respiratory distress	2	0	2
	Rhinalgia	1	0	1
	Rhinorrhoea	1	1	2
	Sputum discoloured	1	0	1
	Throat tightness	0	1	1
	Upper respiratory tract congestion	1	0	1

	Wheezing	1	1	2
Skin and subcutaneous tissue disorders	Angioedema	4	0	4
	Blister	1	1	2
	Cold sweat	2	1	3
	Cutaneous sarcoidosis	1	0	1
	Dry skin	1	0	1
	Erythema	8	7	15
	Erythema nodosum	1	0	1
	Hyperhidrosis	25	10	35
	Lividity	1	0	1
	Night sweats	5	1	6
	Pain of skin	3	1	4
	Petechiae	1	0	1
	Photosensitivity reaction	1	0	1
	Pruritus	14	3	17
	Psoriasis	0	1	1
	Rash	9	5	14
	Rash erythematous	3	1	4
	Rash macular	13	5	18
	Rash maculo-papular	1	0	1
	Rash papular	0	1	1
	Rash pruritic	0	1	1
	Sensitive skin	3	3	6
	Skin burning sensation	1	0	1
	Skin discolouration	0	1	1
	Skin disorder	75	52	127
	Skin reaction	1	2	3
Skin warm	0	1	1	
Urticaria	9	6	15	
Social circumstances	Bedridden	0	1	1
	Housebound	1	0	1
	Walking disability	2	0	2
	Water pollution	1	0	1
Surgical and medical procedures	Bed rest	3	0	3
Vascular disorders	Arteritis	1	0	1
	Artery dissection	1	0	1
	Blood pressure fluctuation	3	2	5
	Circulatory collapse	1	0	1
	Cyanosis	1	0	1
	Deep vein thrombosis	2	0	2
	Diastolic hypertension	1	0	1
	Flushing	1	0	1
	Giant cell arteritis	1	0	1
	Haematoma	3	2	5
	Haemorrhage	2	0	2
	Hot flush	4	5	9
	Hypertension	4	2	6
	Hypertensive crisis	2	0	2
	Hypotension	9	0	9
	Infarction	1	0	1

Lymphoedema	1	0	1
Microangiopathy	0	1	1
Pallor	3	2	5
Peripheral coldness	3	0	3
Phlebitis	1	0	1
Shock	1	0	1
Thrombosis	2	2	4
Varicophlebitis	0	1	1
Varicose vein	1	1	2
Vasculitis	1	0	1
Vein discolouration	1	0	1
Vein disorder	1	0	1
Venous thrombosis	1	1	2
<b>Total</b>	<b>6410</b>	<b>2060</b>	<b>8.470</b>