

Summary Tabulation 01-06-2021

Active Substance (High Level)		COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)		
Reaction SOC	Reaction PT	Serious	Non Serious	Total
Blood and lymphatic system disorders	Anaemia	2	1	3
	Autoimmune haemolytic anaemia	1	0	1
	Coagulopathy	53	23	76
	Coombs negative haemolytic anaemia	1	0	1
	Disseminated intravascular coagulation	1	0	1
	Immune thrombocytopenia	2	0	2
	Leukocytosis	1	0	1
	Leukopenia	1	0	1
	Lymph node pain	1	0	1
	Lymphadenopathy	6	2	8
	Lymphopenia	1	0	1
	Necrotic lymphadenopathy	0	1	1
	Neutropenia	3	1	4
	Splenic embolism	1	0	1
	Splenic infarction	1	0	1
	Thrombocytopenia	24	6	30
Cardiac disorders	Acute cardiac event	1	0	1
	Angina pectoris	2	0	2
	Angina unstable	1	0	1
	Arrhythmia	5	2	7
	Bradycardia	1	2	3
	Cardiac arrest	2	0	2
	Cardiac failure	2	0	2
	Cardiovascular disorder	42	6	48
	Myocardial depression	1	0	1
	Myocardial infarction	2	0	2
	Myocarditis	1	0	1
	Palpitations	35	4	39
	Pericarditis	1	0	1
	Sinus tachycardia	2	0	2
	Tachycardia	33	4	37
Ear and labyrinth disorders	Deafness	2	2	4
	Deafness unilateral	5	1	6
	Ear congestion	0	2	2
	Ear discomfort	3	0	3

	Ear pain	10	2	12
	Hyperacusis	3	0	3
	Meniere's disease	1	0	1
	Sudden hearing loss	0	1	1
	Tinnitus	6	1	7
	Vertigo	32	5	37
Endocrine disorders	Adrenocortical insufficiency acute	1	0	1
	Goitre	1	0	1
Eye disorders	Amaurosis fugax	1	1	2
	Asthenopia	2	0	2
	Blindness	5	1	6
	Blindness unilateral	4	0	4
	Conjunctival haemorrhage	1	1	2
	Diplopia	0	1	1
	Eye disorder	1	0	1
	Eye haemorrhage	2	2	4
	Eye irritation	1	0	1
	Eye oedema	1	0	1
	Eye pain	4	3	7
	Eye swelling	2	0	2
	Macular oedema	1	0	1
	Miosis	1	0	1
	Mydriasis	1	0	1
	Ocular discomfort	1	0	1
	Papilloedema	1	0	1
	Photophobia	5	0	5
	Photopsia	1	0	1
	Pupils unequal	1	0	1
	Retinal artery thrombosis	3	0	3
	Retinal ischaemia	1	0	1
	Retinal vascular thrombosis	0	1	1
	Retinal vein thrombosis	3	0	3
	Swelling of eyelid	0	1	1
	Uveitis	1	0	1
	Vision blurred	13	3	16
	Visual field defect	1	0	1
	Visual impairment	15	4	19
	Visual snow syndrome	1	0	1
Gastrointestinal disorders	Abdominal discomfort	4	0	4
	Abdominal distension	1	0	1
	Abdominal pain	25	6	31
	Abdominal pain upper	16	4	20
	Abnormal faeces	1	0	1
	Aphthous ulcer	0	1	1
	Colitis ischaemic	2	0	2
	Colitis ulcerative	1	0	1
	Constipation	1	0	1
	Crohn's disease	1	0	1
	Diarrhoea	53	8	61
	Diarrhoea haemorrhagic	0	1	1

Dry mouth	6	0	6
Dyspepsia	3	0	3
Dysphagia	1	1	2
Eruption	1	0	1
Faeces discoloured	1	0	1
Faeces soft	1	0	1
Flatulence	1	0	1
Gastrointestinal disorder	4	0	4
Gastrointestinal pain	1	0	1
Gastrooesophageal reflux disease	1	0	1
Gingival bleeding	1	0	1
Glossodynia	1	0	1
Haemorrhoidal haemorrhage	1	0	1
Haemorrhoids thrombosed	1	1	2
Hypoesthesia oral	0	1	1
Intestinal congestion	1	0	1
Intestinal infarction	1	0	1
Intestinal ischaemia	3	0	3
Lip pain	1	0	1
Lip swelling	0	2	2
Melaena	1	0	1
Mesenteric vein thrombosis	1	0	1
Mouth haemorrhage	0	1	1
Nausea	703	48	751
Oesophageal spasm	1	0	1
Oral discomfort	2	0	2
Paraesthesia oral	3	2	5
Rectal haemorrhage	1	2	3
Regurgitation	1	0	1
Retching	3	0	3
Splanchnic hypoperfusion	1	0	1
Swollen tongue	1	1	2
Thrombosis mesenteric vessel	1	0	1
Toothache	0	1	1
Vomiting	76	9	85
General disorders and administration site conditions			
Adverse drug reaction	3	0	3
Adverse event	1	0	1
Application site joint warmth	1	0	1
Asthenia	37	0	37
Axillary pain	2	2	4
Brain death	1	0	1
Chest discomfort	8	2	10
Chest pain	22	6	28
Chills	1272	89	1 361
Condition aggravated	2	0	2
Death	13	0	13
Discomfort	1	0	1
Drug ineffective	0	2	2
Exercise tolerance decreased	2	0	2
Extensive swelling of vaccinated limb	77	11	88

Face oedema	3	0	3
Facial pain	0	1	1
Fatigue	1239	95	1 334
Feeling abnormal	18	2	20
Feeling cold	28	4	32
Feeling drunk	2	1	3
Feeling hot	17	4	21
Feeling of body temperature change	15	2	17
Gait disturbance	4	1	5
Gait inability	2	0	2
General physical health deterioration	5	0	5
Hyperpyrexia	0	1	1
Hyperthermia	2	1	3
Hypothermia	2	0	2
Induration	2	0	2
Inflammation	1	0	1
Influenza like illness	138	14	152
Injected limb mobility decreased	1	0	1
Injection site discomfort	3	0	3
Injection site erythema	15	2	17
Injection site haematoma	2	0	2
Injection site haemorrhage	1	0	1
Injection site hypoesthesia	2	0	2
Injection site induration	6	1	7
Injection site inflammation	1	0	1
Injection site movement impairment	2	0	2
Injection site necrosis	1	0	1
Injection site oedema	1	0	1
Injection site pain	101	6	107
Injection site paraesthesia	1	0	1
Injection site phlebitis	0	1	1
Injection site pruritus	0	1	1
Injection site rash	1	0	1
Injection site reaction	617	47	664
Injection site swelling	17	2	19
Injection site warmth	10	0	10
Local reaction	1	0	1
Localised oedema	1	0	1
Malaise	708	61	769
Multiple organ dysfunction syndrome	1	0	1
No adverse event	1	0	1
Oedema	2	0	2
Oedema peripheral	3	0	3
Pain	20	8	28
Peripheral swelling	60	5	65
Pyrexia	1272	97	1 369
Secretion discharge	1	0	1
Sensation of foreign body	1	0	1
Sudden death	7	0	7
Swelling	5	3	8

	Swelling face	1	0	1
	Tenderness	2	0	2
	Thirst	4	0	4
	Tissue infiltration	0	1	1
	Unevaluable event	1	1	2
	Vaccination site discharge	0	1	1
	Vaccination site erythema	1	0	1
	Vaccination site haematoma	1	0	1
	Vaccination site movement impairment	1	0	1
	Vaccination site pain	2	3	5
Hepatobiliary disorders	Gallbladder necrosis	1	0	1
	Hepatic failure	1	0	1
	Hepatic steatosis	1	0	1
	Hyperbilirubinaemia	1	0	1
	Liver disorder	2	0	2
	Portal vein occlusion	1	0	1
	Portal vein thrombosis	2	0	2
	Venoocclusive liver disease	1	0	1
Immune system disorders	Anaphylactic reaction	7	3	10
	Anaphylactic shock	1	0	1
	Autoimmune disorder	6	0	6
	Hypersensitivity	27	10	37
Infections and infestations	Abscess	0	1	1
	Brain abscess	1	0	1
	Brain empyema	1	0	1
	COVID-19	38	4	42
	Cavernous sinus thrombosis	1	0	1
	Chronic sinusitis	1	0	1
	Conjunctivitis	1	0	1
	Conjunctivitis viral	0	1	1
	Cystitis	1	0	1
	Diverticulitis	1	0	1
	Encephalitis	1	0	1
	Erysipelas	0	1	1
	Herpes zoster	2	6	8
	Influenza	12	9	21
	Injection site cellulitis	0	1	1
	Laryngitis	1	0	1
	Lymphangitis	0	1	1
	Meningitis bacterial	1	0	1
	Nasopharyngitis	13	1	14
	Oral herpes	1	0	1
	Pneumonia	1	0	1
	Pyelonephritis acute	1	0	1
	Respiratory tract infection	1	0	1
	Sepsis	2	0	2
	Septic shock	2	0	2
	Sinusitis	1	0	1
	Streptococcal infection	1	0	1
	Subcutaneous abscess	0	1	1

	Sweating fever	0	1	1
	Tooth abscess	1	0	1
	Urinary tract infection	2	0	2
	Vestibular neuritis	1	0	1
Injury, poisoning and procedural complications	Contusion	7	6	13
	Exposure during pregnancy	0	1	1
	Fall	6	1	7
	Head injury	1	0	1
	Incorrect route of product administration	1	2	3
	Kidney rupture	1	0	1
	Maternal exposure during breast feeding	2	0	2
	Medication error	1	3	4
	Off label use	0	2	2
	Product administration error	0	1	1
	Vasoplegia syndrome	1	0	1
	Venous injury	0	1	1
	Wrong product administered	0	1	1
Investigations	Anti-platelet antibody	1	0	1
	Antibody test negative	0	1	1
	Babinski reflex test	1	0	1
	Blood albumin decreased	1	0	1
	Blood bilirubin increased	1	0	1
	Blood fibrinogen decreased	2	0	2
	Blood glucose abnormal	1	0	1
	Blood pressure decreased	11	1	12
	Blood pressure increased	7	1	8
	Body temperature decreased	2	1	3
	Body temperature increased	5	2	7
	C-reactive protein increased	10	0	10
	Capillary nail refill test abnormal	1	0	1
	Ejection fraction decreased	1	0	1
	Fibrin D dimer increased	14	1	15
	General physical condition abnormal	2	0	2
	Haematocrit decreased	1	0	1
	Haematocrit increased	1	0	1
	Haemoglobin decreased	1	0	1
	Heart rate increased	21	5	26
	Heart rate normal	1	0	1
	Heparin-induced thrombocytopenia test positive	4	0	4
	Interleukin level increased	1	0	1
	Intestinal transit time abnormal	0	1	1
	Liver function test abnormal	1	0	1
	Oxygen saturation decreased	3	0	3
	Platelet count decreased	5	0	5
	Platelet count increased	1	0	1
	Procalcitonin increased	1	0	1
	Red blood cell count decreased	1	0	1
	Red blood cell count increased	0	1	1
	Red blood cell sedimentation rate increased	1	0	1
	Respiratory rate decreased	0	1	1

	SARS-CoV-2 antibody test negative	0	2	2
	SARS-CoV-2 test negative	0	1	1
	Troponin T increased	1	0	1
	Troponin increased	2	0	2
	Venous pressure increased	1	0	1
	Weight decreased	4	0	4
Metabolism and nutrition disorders	Decreased appetite	62	6	68
	Dehydration	2	0	2
	Feeding disorder	1	0	1
	Fluid retention	1	1	2
	Gout	1	0	1
	Hyperkalaemia	1	0	1
	Hypoglycaemia	1	0	1
	Hypovolaemia	1	0	1
	Lactic acidosis	2	0	2
	Oligodipsia	1	0	1
Musculoskeletal and connective tissue disorders	Arthralgia	544	44	588
	Arthritis	4	0	4
	Back pain	24	5	29
	Bone pain	2	0	2
	Fibromyalgia	1	0	1
	Joint stiffness	0	1	1
	Limb discomfort	11	2	13
	Muscle spasms	12	0	12
	Muscle swelling	1	0	1
	Muscle twitching	2	0	2
	Muscular weakness	11	5	16
	Musculoskeletal stiffness	57	1	58
	Myalgia	1065	88	1 153
	Myosclerosis	1	0	1
	Neck pain	16	2	18
	Osteoarthritis	2	1	3
	Pain in extremity	71	14	85
	Spinal deformity	0	1	1
	Spinal pain	0	1	1
	Still's disease	1	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neoplasm malignant	1	0	1
Nervous system disorders	Ageusia	4	0	4
	Altered state of consciousness	4	1	5
	Amnesia	5	0	5
	Anosmia	2	0	2
	Aphasia	5	0	5
	Areflexia	1	0	1
	Balance disorder	8	1	9
	Bell's palsy	1	0	1
	Brain oedema	2	0	2
	Burning sensation	3	0	3
	Carotid artery thrombosis	1	0	1
	Cerebellar stroke	1	0	1
	Cerebral haemorrhage	8	0	8

Cerebral infarction	2	0	2
Cerebral ischaemia	1	0	1
Cerebral mass effect	1	0	1
Cerebral thrombosis	2	0	2
Cerebrovascular accident	6	0	6
Cervical radiculopathy	0	1	1
Coma	1	0	1
Dementia Alzheimer's type	1	0	1
Depressed level of consciousness	4	0	4
Diplegia	1	0	1
Disturbance in attention	7	1	8
Dizziness	46	8	54
Dizziness postural	1	0	1
Dysarthria	3	0	3
Dysgeusia	6	1	7
Dyskinesia	1	0	1
Dysstasia	0	1	1
Electric shock sensation	1	0	1
Facial nerve disorder	1	0	1
Facial paralysis	6	1	7
Formication	0	1	1
Guillain-Barre syndrome	2	0	2
Head discomfort	4	2	6
Headache	1303	112	1 415
Hemianopia	1	0	1
Hemiparaesthesia	0	1	1
Hemiparesis	2	1	3
Hemiplegia	4	0	4
Hyperaesthesia	4	0	4
Hyperreflexia	1	0	1
Hypoesthesia	13	5	18
Intracranial pressure increased	1	0	1
Ischaemic cerebral infarction	1	0	1
Ischaemic stroke	1	0	1
Loss of consciousness	6	1	7
Memory impairment	2	0	2
Meningism	0	1	1
Migraine	23	0	23
Monoplegia	2	0	2
Motor dysfunction	1	0	1
Muscle contractions involuntary	1	0	1
Muscle tone disorder	1	0	1
Nervous system disorder	41	8	49
Neuralgia	2	0	2
Neuropathy peripheral	1	0	1
Pachymeningitis	1	0	1
Paraesthesia	13	6	19
Presyncope	1	1	2
Restless legs syndrome	3	0	3
Sedation	1	0	1

	Seizure	15	6	21
	Sensory loss	2	1	3
	Somnolence	10	2	12
	Speech disorder	3	1	4
	Spinal cord infarction	1	0	1
	Spinal cord ischaemia	1	0	1
	Syncope	14	5	19
	Taste disorder	2	1	3
	Transient ischaemic attack	3	0	3
	Transverse sinus thrombosis	1	0	1
	Tremor	22	5	27
	Unresponsive to stimuli	4	0	4
Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	2	0	2
	Foetal death	1	0	1
	Preterm premature rupture of membranes	1	0	1
Product issues	Oversensing	2	0	2
Psychiatric disorders	Agitation	5	0	5
	Anxiety	3	1	4
	Apathy	2	0	2
	Confusional state	18	0	18
	Daydreaming	1	1	2
	Delirium	1	0	1
	Delusion	0	1	1
	Depressed mood	0	2	2
	Depression	1	0	1
	Disorientation	1	0	1
	Dissociation	0	1	1
	Eating disorder	1	0	1
	Emotional poverty	1	0	1
	Fear of death	1	0	1
	Hallucination	1	1	2
	Hallucination, visual	1	0	1
	Initial insomnia	1	0	1
	Insomnia	31	2	33
	Nightmare	1	1	2
	Panic attack	1	0	1
	Phonophobia	1	0	1
	Psychomotor retardation	1	0	1
	Restlessness	3	0	3
	Stress	1	0	1
Renal and urinary disorders	Acute kidney injury	2	0	2
	Calculus urinary	1	0	1
	Chromaturia	1	0	1
	Dysuria	1	0	1
	Haematuria	1	0	1
	Hydronephrosis	1	0	1
	Incontinence	1	0	1
	Neurogenic bladder	1	0	1
	Pollakiuria	1	0	1
	Polyuria	1	0	1

	Renal colic	2	0	2
	Renal disorder	8	0	8
	Renal failure	1	0	1
	Renal pain	2	0	2
	Renal tubular disorder	1	0	1
	Renal vascular thrombosis	1	0	1
	Urge incontinence	1	0	1
	Urinary incontinence	3	0	3
	Urinary retention	2	0	2
Reproductive system and breast disorders	Amenorrhoea	1	0	1
	Breast cyst	1	0	1
	Breast inflammation	1	0	1
	Breast pain	2	2	4
	Breast swelling	0	1	1
	Dysmenorrhoea	1	0	1
	Ejaculation disorder	0	1	1
	Erectile dysfunction	1	0	1
	Heavy menstrual bleeding	2	0	2
	Menstrual disorder	3	1	4
	Menstruation irregular	1	0	1
	Vaginal haemorrhage	2	0	2
	Varicose veins pelvic	1	0	1
	Vulval haematoma	0	1	1
Respiratory, thoracic and mediastinal disorders	Acute pulmonary oedema	1	0	1
	Apparent life threatening event	1	0	1
	Asthma	4	2	6
	Choking sensation	1	0	1
	Chronic obstructive pulmonary disease	1	0	1
	Cough	26	0	26
	Dysphonia	2	0	2
	Dyspnoea	56	4	60
	Dyspnoea exertional	5	0	5
	Epistaxis	10	2	12
	Hyperventilation	4	0	4
	Lung disorder	2	0	2
	Nasal congestion	2	0	2
	Oropharyngeal pain	11	1	12
	Painful respiration	2	0	2
	Pharyngeal paraesthesia	0	1	1
	Pharyngeal swelling	1	1	2
	Pleural effusion	2	0	2
	Pleurisy	1	0	1
	Productive cough	1	0	1
	Pulmonary embolism	25	1	26
	Pulmonary hypertension	1	0	1
	Pulmonary oedema	2	0	2
	Pulmonary pain	1	1	2
	Rales	1	0	1
	Respiratory depression	1	0	1
	Respiratory disorder	90	13	103

	Respiratory distress	2	0	2
	Rhinorrhoea	2	2	4
	Sneezing	1	0	1
	Stridor	1	0	1
	Tachypnoea	1	0	1
	Throat irritation	1	1	2
	Tonsillar erythema	0	1	1
	Wheezing	2	0	2
Skin and subcutaneous tissue disorders	Angioedema	3	2	5
	Blister	2	0	2
	Cold sweat	2	1	3
	Dermatitis allergic	1	0	1
	Ecchymosis	1	0	1
	Eczema	1	0	1
	Erythema	12	2	14
	Erythema multiforme	0	1	1
	Hyperhidrosis	65	3	68
	Miliaria	2	0	2
	Night sweats	1	2	3
	Pain of skin	9	0	9
	Pemphigoid	1	0	1
	Petechiae	5	3	8
	Photosensitivity reaction	3	0	3
	Pruritus	11	4	15
	Psoriasis	1	0	1
	Purpura	1	1	2
	Rash	4	1	5
	Rash erythematous	4	0	4
	Rash macular	1	0	1
	Rash papular	0	1	1
	Rash pruritic	1	1	2
	Sensitive skin	3	0	3
	Skin discolouration	1	1	2
	Skin disorder	65	25	90
	Skin lesion	0	1	1
	Skin lesion inflammation	1	0	1
	Skin mass	1	0	1
	Skin odour abnormal	1	0	1
	Urticaria	6	4	10
Social circumstances	Bedridden	0	1	1
	Impaired work ability	1	0	1
	Walking disability	1	0	1
Surgical and medical procedures	Bed rest	1	0	1
	Chemotherapy	1	0	1
	Dialysis	1	0	1
	Explorative laparotomy	1	0	1
	Eye laser surgery	1	0	1
	Hospitalisation	0	1	1
	Interchange of vaccine products	0	1	1
Vascular disorders	Arterial thrombosis	1	0	1

Arteriosclerosis	0	1	1
Axillary vein thrombosis	1	0	1
Blood pressure fluctuation	1	0	1
Bloody discharge	1	0	1
Capillary leak syndrome	1	0	1
Cyanosis	2	3	5
Deep vein thrombosis	17	4	21
Flushing	1	0	1
Giant cell arteritis	1	0	1
Haematoma	5	5	10
Haemodynamic instability	1	0	1
Haemorrhage	1	0	1
Hot flush	11	0	11
Hypertension	23	3	26
Hypertensive crisis	2	0	2
Hypotension	20	3	23
Hypovolaemic shock	2	0	2
Infarction	1	0	1
Ischaemia	1	0	1
Jugular vein thrombosis	2	0	2
Pallor	1	0	1
Pelvic venous thrombosis	0	1	1
Peripheral coldness	3	1	4
Peripheral ischaemia	1	0	1
Peripheral vascular disorder	1	0	1
Peripheral venous disease	1	1	2
Periphlebitis	0	1	1
Phlebitis	2	3	5
Phlebitis superficial	0	1	1
Subclavian artery thrombosis	1	0	1
Subclavian vein thrombosis	1	0	1
Thrombophlebitis	2	0	2
Thrombophlebitis superficial	5	2	7
Thrombosis	11	4	15
Varicose vein	1	1	2
Vascular pain	0	1	1
Vascular rupture	1	0	1
Vasodilatation	1	1	2
Vein disorder	1	0	1
Vein rupture	1	0	1
Venous aneurysm	0	1	1
Venous thrombosis	3	1	4
Venous thrombosis limb	1	1	2
Total	11660	1215	12 875