RP	Initial_Follow_up	Case_ID	Country	Patient_Gender	Initial_Receipt_Date	Last_Report_Receipt_Date	Patient_Age__Years_	Batch_Lot_Number	WW_Identifier	Event_Outcome	Concomitant_Medications	Medical_History	ALL_PTs
Review Period	Initial	[redacted]	[redacted]	Unknown	2-Jan-22	14-Jan-22	.		[redacted]	Fatal	FOLIC ACID	Pregnancy(H); Body mass index(H); Pregnancy(H); Glucose tolerance test(H); Blood pressure measurement(H); COVID-19 VACCINE ASTRAZENECA; SARS-CoV-2 test(H)	Foetal exposure during pregnancy, Stillbirth
Review Period	Initial		GERMANY	Male	5-Jan-22	.	33	042G21A		Fatal		Seasonal allergy(C); COMIRNATY; COMIRNATY	Angina pectoris, Dyspnoea, Influenza like illness, Loss of consciousness, Resuscitation
Review Period	Initial		GERMANY	Male	5-Jan-22	.	60	000114A		Fatal		COVID-19 VACCINE JANSSEN	Cardiovascular disorder, Resuscitation
Review Period	Initial		UNITED KINGDOM	Female	5-Jan-22	6-Feb-22	63	3004675		Fatal	COVID-19 VACCINE ASTRAZENECA; COVID-19 VACCINE ASTRAZENECA; ASPIRIN [ACETYLSALICYLIC ACID]; CETIRIZINE HYDROCHLORIDE; LISINOPRIL; LEVOTHYROXINE; MEMANTINE; DONEPEZIL HYDROCHLORIDE	Vascular dementia(C); Steroid therapy; Colostomy	Cardiac arrest, Deep vein thrombosis, Haematochezia, Pain in extremity, Pulmonary thrombosis, Transient ischaemic attack
Review Period	Initial		NETHERLANDS	Male	5-Jan-22	.	63	093F21A		Fatal		ASTRAZENECA COVID-19 VACCINE; ASTRAZENECA COVID-19 VACCINE	Arrhythmia, Cardiac arrest
Review Period	Initial		GERMANY	Male	5-Jan-22	.	.	3004951		Fatal		COMIRNATY	Cardiovascular symptom, Cerebrovascular accident, Pulmonary embolism
Review Period	Initial		UNITED KINGDOM	Female	9-Jan-22	18-Jan-22	63	3004732		Fatal	COVID-19 VACCINE ASTRAZENECA; COVID-19 VACCINE ASTRAZENECA	Animal bite(H)	Arrhythmia, Cardiomyopathy, Death, Electrocardiogram abnormal, Myocarditis, Palpitations, Paroxysmal arrhythmia
Review Period	Initial		GERMANY	Male	10-Jan-22	.	67			Fatal		COVID-19 VACCINE ASTRAZENECA(H); COMIRNATY(H)	Breast pain, Sudden death
Review Period	Initial		KOREA, REPUBLIC OF	Male	11-Jan-22	.	35			Fatal		Intellectual disability(C); ASTRAZENECA COVID-19 VACCINE; ASTRAZENECA COVID-19 VACCINE	Decreased appetite, Interchange of vaccine products, Loss of consciousness, Salivary hypersecretion, Sudden death
Review Period	Initial		NETHERLANDS	Male	11-Jan-22	22-Jan-22	73	044G21ABS		Fatal	ACETYLSALICYLZUUR	PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE	Malaise, Myalgia, Sudden cardiac death
Review Period	Initial		UNITED KINGDOM	Unknown	11-Jan-22	11-Jan-22	.	3005287		Fatal	COVID-19 VACCINE ASTRAZENECA		Fatigue, Sudden death
Review Period	Initial		FRANCE	Female	13-Jan-22	.	80	3005242		Fatal	COMIRNATY	Obesity(H); Hypertension(C)	Immunisation reaction, Sudden death
Review Period	Initial		NETHERLANDS	Female	13-Jan-22	28-Jan-22	.			Fatal	SIMVASTATINE; COLECALCIFEROL; UMECLIDINIUM; AZITROMYCINE	COVID-19(H); Arteriovenous malformation(H); Cerebellar haemorrhage(H); PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE	Cerebral haemorrhage
Review Period	Initial		FRANCE	Male	15-Jan-22	.	85	3005242		Fatal	COMIRNATY	Cardiac failure(C); Diabetes mellitus(C); Hypertension(C); Arrhythmia(H); Hypoacusis(H); Silicosis(H); Hepatic mass(H); Ventricular dysfunction(C); Inguinal hernia(H)	Death
Review Period	Initial		FRANCE	Male	14-Jan-22	.	86	057G21A		Fatal		Osteoporotic fracture(H); Polymyalgia rheumatica(H); Peripheral arterial occlusive disease(H); PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE	Death
Review Period	Initial		GERMANY	Male	21-Jan-22	.	53	007G21A		Fatal		Hypertension(C); Tobacco user(C); COMIRNATY; COMIRNATY	Death, Nausea, Vomiting
Review Period	Initial		GERMANY	Male	21-Jan-22	.	52	3005291		Fatal		COMIRNATY; COMIRNATY	Cardiac arrest
Review Period	Initial		UNITED STATES	Male	14-Jan-22	.	.			Fatal			Myocardial infarction
Review Period	Initial		GERMANY	Female	21-Jan-22	.	90			Fatal		COMIRNATY; Dementia(C)	Death
Review Period	Initial		GERMANY	Female	21-Jan-22	.	85	000128A		Fatal		COMIRNATY(H)	Arrhythmia
Review Period	Initial		UNITED KINGDOM	Female	21-Jan-22	3-Feb-22	51			Fatal	COVID-19 VACCINE ASTRAZENECA; COVID-19 VACCINE ASTRAZENECA; AMITRIPTYLINE; NARATRIPTAN	Lumbar puncture(H); Non-tobacco user(H); Migraine(H)	Deep vein thrombosis, Headache, Nausea, Pulmonary embolism, Syncope

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Review Period	Initial	[redacted]	NETHERLANDS	Female	22-Jan-22	########	77		[redacted]	Fatal	AZITROMYCINE; INSULIN; HYDROCHLOORTHIAZIDE	Pancreatitis(H); Obesity(H); Radius fracture(H); Dyspnoea(H); Type 1 diabetes mellitus(H); Trigger finger(H); Cholangitis(H); Tibia fracture(H); Tendon sheath incision(H); Agoraphobia(H); Cholelithiasis(H); PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE; Hypertension(C); Neurolysis	Abdominal pain, Blood glucose fluctuation, Circulatory collapse, Diarrhoea, Gastrointestinal pain, Haematochezia, Headache, Rectal haemorrhage, Resuscitation, Sinusitis, Vomiting
Review Period	Initial		NETHERLANDS	Female	22-Jan-22	########	80			Fatal	METFORMINE [METFORMIN]; FRUSEMIDE [FUROSEMIDE]; ACENOCOUMAROL; INSULINE NPH; OMEPRAZOL A; ATORVASTATINE [ATORVASTATIN]; GLIMEPIRIDE; VALSARTAN; PAROXETIN [PAROXETINE]; METOPROLOL;MORPHINE; BARNIDIPINE	Atrial fibrillation(C); Diabetes mellitus(C); Obesity(C); Vertigo positional(C); Hypertension(C); Dizziness postural(C); Myocardial infarctioo(H); COMIRNATY; COMIRNATY	Myocardial infarction
Review Period	Initial		NORWAY	Female	25-Jan-22	########	55	094F21A		Fatal		Gastric ulcer(C); Transaminases increased(C); Humerus fracture(H); Patella fracture(H); Jaw fracture(H); Splenic rupture(H); Osteopenia(C); Tobacco user(C); Hand fracture(H); Alcobol problem(C); Intervertebral disc protrusion(C); Cholecystitis(C); Radius fracture(H); COMIRNATY; COMIRNATY	Sudden death
Review Period	Initial		UNITED STATES	Unknown	26-Jan-22	.	49			Fatal			Myocardial infarction
Review Period	Initial		UNITED STATES	Female	27-Jan-22	.	66			Fatal	PLAVIX	PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE	Discomfort, Dizziness, Feeling of body temperature change, Pulmonary thrombosis
Review Period	Initial		GERMANY	Female	27-Jan-22	.	78			Fatal		Adrenal insufficiency(H); Autoimmune thyroiditis(H); Vitamin B12 deficiency(H); VAXZEVRIA; COMIRNATY	Asthenia, Death, Dehydration, Diarrhoea, Dizziness, Malaise, Nausea
Review Period	Initial		ITALY	Male	28-Jan-22	29-Jan-22	59	094F21A		Fatal		COMIRNATY; COMIRNATY	Sudden death
Review Period	Initial		FRANCE	Female	28-Jan-22	.	61			Fatal	COMIRNATY	Ex-tobacco user(H)	Ventricular fibrillation
Review Period	Initial		JAPAN	Female	27-Jan-22	4-Feb-22	68	3005840		Fatal		COMIRNATY; COMIRNATY	Aortic dissection, Cardio-respiratory arrest, Dyspnoea
Review Period	Initial		UNITED KINGDOM	Male	28-Jan-22	2-Feb-22	79			Fatal	ATORVASTATIN; PFIZER BIONTECH COVID-19 VACCINE; DOXYCYCLINE; MORPHINE; SALBUTAMOL	Pulmonary fibrosis(H); Lower respiratory tract infection(H); Dyspnoea(H); Hypertension(C); Oxygen saturation decreased(H); Arthritis(H); (H); COVID-19(H)	Hypertension, Oxygen saturation decreased, Pyrexia, Tachycardia
Review Period	Initial		GERMANY	Male	31-Jan-22	.	83	3001651		Fatal		COVID-19 VACCINE(H); COVID-19 VACCINE(H)	Atonic seizures, Drop attacks, Pyrexia, Sudden death
Review Period	Initial		GERMANY	Female	1-Feb-22	.	69	000105A		Fatal		COVID-19(C); VAXZEVRIA; COMIRNATY	Coagulopathy, COVID-19, Hepatic failure, Multiple organ dysfunction syndrome, Shock haemorrhagic, Thrombocytopenia
Review Period	Initial		GERMANY	Pemale	1-Feb-22	.	47	045G21A		Fatal		COMIRNATY; COMIRNATY	Cerebral infarction, Cerebrovascular accident
Review Period	Initial		FRANCE	Male	1-Feb-22	.	48	018G21A		Fatal	COMIRNATY		Sudden death
Review Period	Initial		FRANCE	Male	1-Feb-22	.	63			Fatal			Cardio-respiratory arrest
Review Period	Initial		GERMANY	Male	1-Feb-22	7-Feb-22	63	045G21A		Fatal		COMIRNATY; VAXZEVRIA	Sudden death
Review Period	Initial		FRANCE	Male	1-Feb-22	########	76	300042722 &		Fatal		Sleep apnoea syndrome(C); Renal transplant; Gout(C); Deafness bilateral(C); Deep vein thrombosis(C); Myocardial ischaemia(C); Dyslipidaemia(C); Hypertension(C); Coronary artery bypass; Optic ischaemic neuropathy(C); Atrioventricular block complete(C)	Vaccination failure
Review Period	Initial		NETHERLANDS	Male	1-Feb-22	9-Feb-22	64	018J21A		Fatal		ASTRAZENECA COVID-19 VACCINE; ASTRAZENECA COVID-19 VACCINE	Pulmonary embolism
Review Period	Initial		GERMANY	Female	2-Feb-22	.	70			Fatal		COVID-19 VACCINE ASTRAZENECA; COMIRNATY	Sudden death

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Review Period	Initial	[redacted]	GERMANY	Male	2-Feb-22	.	67	3004951	[redacted]	Fatal		VAXZEVRIA; COMIRNATY	Sudden death
Review Period	Initial	[redacted]	NETHERLANDS	Male	1-Feb-22	########	84		[redacted]	Fatal	LENDORMIN; OXYCODON; B IJZER NUTRIDOSES; ANTICOAGULANT CITRATE DEXTROSE; CODEINE SULPHATE	Pulmonary embolism(H); Arrhythmia(H); Pneumonia(H); Pulmonary oedema(H); Oesophageal cancer metastatic(C); COMIRNATY; COMIRNATY	Pneumonia
Review Period	Initial	[redacted]	GERMANY	Male	2-Feb-22	.	56	000120A	[redacted]	Fatal		COMIRNATY; COMIRNATY	Cerebral haemorrhage
Review Period	Initial	[redacted]	NETHERLANDS	Female	1-Feb-22	24-Jun-22	84	093F21A	[redacted]	Fatal	PAROXETIN [PAROXETINE]; METOPROLOL SUCCINAT BETA; ACETYLSALICYLZUUR; CHLOORTALIDON	Hypersensitivity; Fall(H); Urinary bladder polyp(H); Breast cancer(H); Intermittent claudication(H); Stent placement; PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE; Cataract(H); Urogenital prolapse(H); Hypertension(H); Cognitive disorder(H)	Cerebral infarction, Dysarthria, Dysphagia, Loss of consciousness, Pneumonia
Review Period	Initial	[redacted]	SPAIN	Male	3-Feb-22	.	48		[redacted]	Fatal	LIXIANA; COMIRNATY	Obesity(C); Sleep apnoea syndrome(C); Deep vein thrombosis(C); Factor V Leiden mutation(C); Migraine(C)	Cardio-respiratory arrest, Pulmonary thrombosis, Thrombocytopenia
Review Period	Initial	[redacted]	GERMANY	Male	4-Feb-22	.	47	3004500	[redacted]	Fatal		COMIRNATY; COMIRNATY	Acute coronary syndrome, Brain injury, Cardiac arrest
Review Period	Initial	[redacted]	GERMANY	Male	7-Feb-22	.	80	092F21A	[redacted]	Fatal		Atrial fibrillation(C); BNT162B2; BNT162B2	Cerebral infarction, Cerebrovascular accident, Hemiparesis
Review Period	Initial	[redacted]	JAPAN	Female	4-Feb-22	.	77	3006279	[redacted]	Fatal	TEGAFUR;URACIL	Uterine cancer(C); Rectal cancer(C); Metastases to lymph nodes(C); COMIRNATY; COMIRNATY	Drowning, Listless, Somnolence
Review Period	Initial	[redacted]	BELGIUM	Male	7-Feb-22	.	46		[redacted]	Fatal		COMIRNATY; COMIRNATY	Chest pain, COVID-19 immunisation, Death
Review Period	Initial	[redacted]	[redacted]	Unknown	7-Feb-22	.	.	3004959	[redacted]	Fatal		COVID-19 VACCINE JANSSEN	Congenital cardiovascular anomaly, Congenital central nervous system anomaly, COVID-19 immunisation, Foetal exposure during pregnancy, Hydronephrosis
Review Period	Initial	[redacted]	JAPAN	Female	7-Feb-22	.	53	3005892	[redacted]	Fatal		Asthma(C); Rheumatic disorder(H); COMIRNATY; COMIRNATY	Cardio-respiratory arrest, Death, Depressed level of consciousness, Pyrexia
Review Period	Initial	[redacted]	JAPAN	Female	3-Feb-22	#########	87	3005694	[redacted]	Fatal	RABEPRAZOLE SODIUM; MAGMITT; NINJIN'YOEITO	Gastrooesophageal reflux disease(C); Constipation(C); Decreased appetite(C); Decreased activity(C); COMIRNATY; COMIRNATY	Chills, Depressed level of consciousness, Feeling cold, Pallor, Pyrexia, Respiratory arrest
Review Period	Initial	[redacted]	ITALY	Female	7-Feb-22	7-Mar-22	77	3005887	[redacted]	Fatal	TRITTICO; LASIX P; TORVAST; FLUVION; CETIRIZINE; COUMADIN; LANSOX; ZAROXOLYN; CALCITRIOL; ZOLOFT; BISOPROLOL; ABASAGLAR; EUTIROX	Cholelithiasis(H); Acute myeloid leukaemia(H); Type 2 diabetes mellitus(C); Hypothyroidism(C); Chronic kidney disease(C); Cardiac failure(C); Humerus fracture(H); Cerebrovascular accident(H); COMIRNATY; COMIRNATY	Acute kidney injury, Cardiomegaly, Generalised oedema, Shock
Review Period	Initial	[redacted]	TAIWAN, PROVINCE OF CHINA	Female	7-Feb-22	.	60	050F21A	[redacted]	Fatal		ASTRAZENECA COVID-19 VACCINE	Adverse drug reaction, Cardiac arrest
Review Period	Initial	[redacted]	TAIWAN, PROVINCE OF CHINA	Female	7-Feb-22	########	61	072F21A_11	[redacted]	Fatal		Dialysis; Diabetes mellitus(C); Hypertensioo(C); ASTRAZENECA COVID-19 VACCINE; ASTRAZENECA COVID-19 VACCINE	Syncope
Review Period	Initial	[redacted]	TAIWAN, PROVINCE OF CHINA	Female	7-Feb-22	.	63	050F21A_11	[redacted]	Fatal		End stage renal disease(C); Type 2 diabetes mellitus(C); Hypertension(C); Viral hepatitis carrier(C); Haemodialysis; ASTRAZENECA COVID-19 VACCINE; ASTRAZENECA COVID-19 VACCINE	Syncope
Review Period	Initial	[redacted]	JAPAN	Male	8-Feb-22	########	86	3005786	[redacted]	Fatal	NEXIUM EBB; RUPAFIN; MEMANTINE HYDROCHLORIDE OD; SERTRALINE; BAYASPIRIN; ZOLPIDEM TARTRATE; CELECOXIB; AMLODIPINE	Hypertension(C); Diabetes mellitus(C); COMIRNATY; COMIRNATY; Eczema(C); Dementia(C); Insomnia(C); Cerebral infarction(C); Cardiac failure chronic(C); Back pain(C); Femoral neck fracture(H); Spinal compression fracture(H)	Acute myocardial infarction, Cardio-respiratory arrest, Feeling abnormal, Malaise
Review Period	Initial	[redacted]	TAIWAN, PROVINCE OF CHINA	Female	7-Feb-22	#########	72		[redacted]	Fatal		Diabetes mellitus(C); Dialysis; ASTRAZENECA COVID-19 VACCINE; ASTRAZENECA COVID-19 VACCINE	Headache, Syncope, Vomiting

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Review Period	Initial	[redacted]	TAIWAN, PROVINCE OF CHINA	Male	7-Feb-22	########	72		[redacted]	Fatal		Transplant failure(H); Coronary artery disease(C); Mitral valve incompetence(C); Coronary artery bypass; Coronary arterial stent insertion; End stage renal disease(C); Stent placement; ASTRAZENECA COVID-19 VACCINE; Dialysis; Stent placement(H)	Asthma, Chest discomfort
Review Period	Initial	[redacted]	TAIWAN, PROVINCE OF CHINA	Female	7-Feb-22	.	86	072F21A_11	[redacted]	Fatal		Bronchiectasis(C); ASTRAZENECA COVID-19 VACCINE; ASTRAZENECA COVID-19 VACCINE	Decreased appetite, Pyrexia
Review Period	Initial	[redacted]	NETHERLANDS	Female	8-Feb-22	########	82		[redacted]	Fatal	CALCIUMCARBIMIDUM; FENTANYL CT; IPRATROPIUM BR; LIDOCAINE NMD; SIMVASTATINE; DENOSUMAB; GABAPENTINE; LEVETIRACETAM TEVA	Sbort stature(C); Embolism venous(H); Gastrooesophageal reflux disease(H); Epilepsy(C); Post herpetic neuralgia(H); Hypertension(C); Osteoporosis(C); Renal impairment(H); Syncope(H); PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE; INFLUENZA VACCIN	Cardiac arrest, Chills, Malaise
Review Period	Initial	[redacted]	GERMANY	Female	9-Feb-22	.	78	216045	[redacted]	Fatal		Atrial fibrillation(H); Quadriplegia(H); Pulmonary fibrosis(H); COVID-19(H); Venous thrombosis limb(H); Myopathy(H); COMIRNATY	Death, Influenza like illness
Review Period	Initial	[redacted]	NETHERLANDS	Male	9-Feb-22	########	77	094F21A	[redacted]	Fatal		COMIRNATY; COMIRNATY; Cerebrovascular accident(H)	Circulatory collapse, Dyspnoea, Myocardial infarction, Pallor
Review Period	Initial	[redacted]	GERMANY	Male	########	.	51	042G21A	[redacted]	Fatal		COMIRNATY; COMIRNATY	Cardiac discomfort, Death, Dyspnoea, Myalgia
Review Period	Initial	[redacted]	NETHERLANDS	Female	9-Feb-22	########	87	216041	[redacted]	Fatal		COMIRNATY; COMIRNATY; Skin ulcer(H); Hypertension(C); Hypoacusis(H); Parkinsonian gait(C); Walking aid user(C); Weight decreased(H); Hypothyroidism(H); Cataract(H); METOPROLOL(H); HYDROCHLOORTHIAZIDE(H); HYDROCHLOORTHIAZIDE(H)	Sudden death
Review Period	Initial	[redacted]	SPAIN	Male	2-Feb-22	########	58	216035	[redacted]	Fatal	COMIRNATY	Nicotine dependence(H); Hypertension(H)	Cardio-respiratory arrest, COVID-19 immunisation, Infarction
Review Period	Initial	[redacted]	GERMANY	Male	########	.	40		[redacted]	Fatal		COMIRNATY	Sudden cardiac death
Review Period	Initial	[redacted]	GERMANY	Male	7-Feb-22	.	63	045G21A	[redacted]	Fatal		Somatic symptom disorder(H); COMIRNATY; VAXZEVRIA	Sudden death
Review Period	Initial	[redacted]	NETHERLANDS	Female	########	########	69		[redacted]	Fatal	PERINDOPRIL GA; LORAZEPAMUM	Throat cancer(H); Hypertension(C); Basal cell carcinoma(H); Tobacco user(C); Breast cancer(H); COMIRNATY; COMIRNATY	Cerebellar haemorrhage, Cerebral haemorrhage, Cerebral infarction, Device dislocation, Partial seizures
Review Period	Initial	[redacted]	ITALY	Male	########	########	87	3006322	[redacted]	Fatal	NORVASC; KANRENOL; TRITTICO; QUETIAPINE; FOSTER [PIROXICAM]	Chronic obstructive pulmonary disease(C); Hypertension(C); Cognitive disorder(H); Chronic kidney disease(C); COMIRNATY; COMIRNATY	Acute kidney injury, Aphasia, Bladder sphincter atony, Cerebrovascular accident, Coma, Pneumonia, Respiratory failure, Septic shock
Review Period	Initial	[redacted]	ICELAND	Male	########	########	74		[redacted]	Fatal			COVID-19 immunisation, COVID-19 pneumonia, Deep vein thrombosis, Immune system disorder, Organ failure, Pneumonia, Pulmonary embolism, Pyrexia, Respiratory failure, SARS-CoV-2 test positive
Review Period	Initial	[redacted]	NORWAY	Male	########	.	71		[redacted]	Fatal	DARATUMUMAB; BORTEZOMIB; DEXAMETHASONE	Chronic kidney disease(H); Chronic obstructive pulmonary disease(H); Cardiac failure(H); Emphysema(H); Plasma cell myeloma(H); Comirnaty; Comirnaty	Atrial fibrillation, Cardiac failure, COVID-19 immunisation, Endotracheal intubation, Renal failure, Respiratory failure, Staphylococcal sepsis, Tachycardia
Review Period	Initial	[redacted]	FRANCE	Male	########	.	89	3004834	[redacted]	Fatal	KARDEGIC; LOVENOX HP; PANTOPRAZOLE; BISOCE; FINASTERIDE; TAHOR	Aortic aneurysm(H); Coronary arterial stent insertion; Carotid arteriosclerosis(H); Hypertension(H); Myocardial infarction(H); Cardiac assistance device user(H); Atrial fibrillation(H); Nicotine dependence(C)	COVID-19 pneumonia, Vaccination failure
Review Period	Initial	[redacted]	JAPAN	Male	########	########	42	3006277	[redacted]	Fatal		Epilepsy(C); Intellectual disability(C); Constipation(C); Infectious pleural effusion(C); COMIRNATY; COMIRNATY	Blood pressure decreased, Cardio-respiratory arrest, Dehydration, Diarrhoea, Gastroenteritis, Loss of consciousness, Pneumonia aspiration, Pyrexia, Vomiting
Review Period	Initial	[redacted]	JAPAN	Male	########	########	76		[redacted]	Fatal		COMIRNATY; COMIRNATY; Diabetes mellitus(C); Atrial fibrillation(C)	Altered state of consciousness, Cerebral infarction, Heat illness, Movement disorder, Multiple organ dysfunction syndrome, Shock
Review Period	Initial	[redacted]	JAPAN	Male	########	########	88	3006279	[redacted]	Fatal		Neoplasm malignant(C); Comirnaty; Comirnaty; Prostate cancer(C); Cerebral infarction(H)	Death, Pyrexia, Respiratory arrest, Sputum increased

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Review Period	Initial	[redacted]	ITALY	Male	########	7-Mar-22	74	3005887	[redacted]	Fatal	TOUJEO; TORVAST; CARDIOASPIRIN; LANOXIN; ELIQUIS; LASIX P; SERTRALINE; KANRENOL; SEQUACOR; LANSOX; NOVORAPID	Respiratory failure(H); Amnestic disorder(H); Ex-tobacco user(H); Diabetic retinopathy(C); Sepsis(H); Diaphragmatic hernia(H); Peripheral arterial occlusive disease(H); Aortic valve replacement(H); Lactic acidosis(H); Hypertensive heart disease(H); Anaemia(H); Insulin-requiring type 2 diabetes mellitus(C); Hypertension(C); Hyperuricaemia(H); Atrial fibrillation(C); Hepatic steatosis(H); Acute pulmonary oedema(H); Cerebral infarction(H); Femur fracture(H); COMIRNATY; COMIRNATY	Anuria, Multiple organ dysfunction syndrome, Septic shock
Review Period	Initial		NORWAY	Male	########	.	58	3006273		Fatal		Overweight(H); Hypercholesterolaemia(C); Hypertension(C); SPIKEVAX; COMIRNATY	Cardiac failure congestive, Circulatory collapse
Review Period	Initial		GERMANY	Male	########	.	57	3004233		Fatal		Hypertension(C); COMIRNATY; COMIRNATY	Death
Review Period	Initial		UNITED KINGDOM	Male	########	6-Mar-22	48			Fatal		SARS-COV-2 VACCINE(H); SARS-COV-2 VACCINE(H)	Cerebral haemorrhage, Headache, Pain in extremity
Review Period	Initial		SPAIN	Male	########	.	62	016G21A		Fatal		Neoplasm prostate(H)	Cerebral haemorrhage, Immune thrombocytopenia
Review Period	Initial		GERMANY	Male	########	.	81	3004235		Fatal		COMIRNATY	Condition aggravated, Decreased appetite, Vomiting, Weight decreased
Review Period	Initial		FRANCE	Male	########	5-May-22	66	214022		Fatal		Abdominal hernia(C); Non-Hodgkin's lympboma(C); Psoriasis(C); Hypercbolesterolaemia(C); Cyst(C); Carpal tunnel syndrome(C); Sinusitis(C); Aortic valve incompetence(C); Tendon disorder(C)	Drug ineffective, Vaccination failure
Review Period	Initial		JAPAN	Male	########	########	85	3005786		Fatal		Hypertension(C); Cerebral infarction(H); COMIRNATY; COMIRNATY	Cardio-respiratory arrest, Contusion, Epistaxis
Review Period	Initial		JAPAN	Male	########	########	80			Fatal		Angina pectoris(C); COMIRNATY; COMIRNATY	Arrbythmia, Cardio-respiratory arrest
Review Period	Initial		JAPAN	Male	########	########	73	000020A		Fatal	NIFEDIPINE; GLIMEPIRIDE; APRINDINE HYDROCHLORIDE; METFORMIN HYDROCHLORIDE; VOGLIBOSE	Diabetes mellitus(C); Hypertension(C); Cerebral infarction(C); COMIRNATY; COMIRNATY	Cardiac arrest, Cardiac death, Myocardial infarction, Poriomania, Thrombosis, Wound
Review Period	Initial		JAPAN	Male	########	########	81	000021A		Fatal		COMIRNATY(H); COMIRNATY(H)	Myocarditis, Sbock
Review Period	Initial		SWEDEN	Female	########	########	95	016G21A		Fatal			Death, Interchange of vaccine products, Off label use
Review Period	Initial		FRANCE	Male	########	.	65	091F21A		Fatal	COMIRNATY	Hypertension(C); Benign prostatic hyperplasia(C); Osteoarthritis(C); COMIRNATY; COMIRNATY	Death
Review Period	Initial		NETHERLANDS	Male	########	########	72			Fatal		Pneumonia(H); Tobacco user(C); Aortic aneurysm(H); Chronic obstructive pulmonary disease(C); Renal cancer(H); COMIRNATY; COMIRNATY	Asthenia, Chills, Cough, Insomnia, Malaise, Myalgia, Nasopharyngitis, Nausea, Peripheral coldness, Vomiting
Review Period	Initial		NETHERLANDS	Male	########	.	82	216036		Fatal	METOPROLOL-BC; SALBUTAMOL A; TIOTROPIUM; ACETYLSALICYLZUUR	Hypertension(C); Resuscitation(H); Aortic aneurysm(H); Atrial fibrillation(C); Coronary artery bypass; Cardiac assistance device user(C); Percutaneous coronary intervention; Wheelchair user(C); Ex-tobacco user(H); Drug bypersensitivity; Aortic aneurysm repair; Plasmacytoma(C); COMIRNATY; COMIRNATY; COMIRNATY; COMIRNATY	Cerebrovascular accident, Respiratory acidosis
Review Period	Initial		JAPAN	Female	########	9-Mar-22	102	000012A		Fatal		COMIRNATY; COMIRNATY	Aortic dissection, Cardio-respiratory arrest, Fall, Headache, Loss of consciousness
Review Period	Initial		GERMANY	Male	########	.	69			Fatal		COVID-19 VACCINE ASTRAZENECA; COMIRNATY	Meningitis, Multiple organ dysfunction syndrome
Review Period	Initial		GERMANY	Male	1-Mar-22	.	64	000137A		Fatal		COMIRNATY; COMIRNATY	Death, Pulmonary embolism
Review Period	Initial		GERMANY	Male	1-Mar-22	.	61	000136A		Fatal		Hypertension(H); COMIRNATY; COVID-19 VACCINE ASTRAZENECA	Cardiac arrest, Death
Review Period	Initial		GERMANY	Male	1-Mar-22	.	67	3004951		Fatal		Cerebrovascular accident(H); JANSSEN COVID-19 VACCINE	Cerebrovascular accident

RP	Initial_Follow_up	Case_ID	Country	Patient_Gender	Initial_Receipt_Date	Last_Report_Receipt_Date	Patient_Age__Years_	Batch_Lot_Number	WW_Identifier	Event_Outcome	Concomitant_Medications	Medical_History	ALL_PTs
Review Period	Initial	[redacted]	GERMANY	Male	3-Mar-22	.	60	045G21A	[redacted]	Fatal		COMIRNATY; COMIRNATY	Death
Review Period	Initial	[redacted]	LUXEMBOURG	Female	3-Mar-22	.	83	017G21A	[redacted]	Fatal		Lymphoma(C); Coagulopathy(H); Cerebrovascular accident(H); Thyroidectomy; Transfusion; Transient ischaemic attack(H); COMIRNATY	COVID-19 immunisation, Dyspnoea, Hypoxia, Pyrexia
Review Period	Initial	[redacted]	PHILIPPINES	Male	3-Mar-22	.	65	061621A	[redacted]	Fatal			Gun shot wound
Review Period	Initial	[redacted]	JAPAN	Female	3-Mar-22	########	88	3005785	[redacted]	Fatal	AMLODIPINE; ALFAROL; DEBERZA; OLMETEC; BETANIS; OMEPRALAN; BILANOA; PARMODIA; METHYCOBAL; TARLIGE; JUVELA N	Rhinitis allergic(C); Diabetes mellitus(C); Hypertension(C); Dyslipidaemia(C); Osteoporosis(C); Cerebral infarction(H); Cerebral haemorrhage(H); Diabetes mellitus(C); Hypertension(C); Dyslipidaemia(H); Hypertonic bladder(H); Gastrooesophageal reflux disease(H); Neuropathy peripheral(C); Neuralgia(C); COMIRNATY; COMIRNATY; Peripheral vascular disorder(C)	Cardiac valve disease
Review Period	Initial	[redacted]	GERMANY	Male	4-Mar-22	########	49	214008	[redacted]	Fatal		COMIRNATY; ASTRAZENECA COVID-19 VACCINE; Substance use(C); Depression(H); Asthma(C)	Cerebral haemorrhage
Review Period	Initial	[redacted]	THAILAND	Female	7-Mar-22	########	50	049F21A	[redacted]	Fatal		CORONAVAC; CORONAVAC; PFIZER BIONTECH COVID-19 VACCINE	Aplastic anaemia, Circulatory collapse, Decreased immune responsiveness, Febrile neutropenia, Haemoptysis, Hepatic failure, Klebsiella sepsis, Renal failure, Wound haemorrhage
Review Period	Initial	[redacted]	GERMANY	Female	7-Mar-22	.	64		[redacted]	Fatal		COMIRNATY(H); VAXZEVRIA(H)	Brain injury, Myocarditis, Resuscitation, Ventricular fibrillation
Review Period	Initial	[redacted]	GERMANY	Male	8-Mar-22	.	58	000077A	[redacted]	Fatal		COMIRNATY; COMIRNATY	Acute myocardial infarction
Review Period	Initial	[redacted]	JAPAN	Male	4-Mar-22	########	29	3005286	[redacted]	Fatal		COMIRNATY; COMIRNATY	Arrhythmia, Cardio-respiratory arrest, Haemorrhage, Incontinence, Pulseless electrical activity, Pyrexia, Syncope, Ventricular fibrillation
Review Period	Initial	[redacted]	JAPAN	Female	7-Mar-22	########	74	3005786	[redacted]	Fatal		COMIRNATY; COMIRNATY	Death
Review Period	Initial	[redacted]	FRANCE	Male	7-Mar-22	.	66	214022	[redacted]	Fatal		Blood cholesterol increased(C); Abdominal hernia(H); Carpal tunnel syndrome(H); Tendon disorder(H); Sinusitis(H); Psoriasis(H); Cyst(H); Aortic valve incompetence(H)	Drug ineffective, Vaccination failure
Review Period	Initial	[redacted]	FRANCE	Male	8-Mar-22	.	55		[redacted]	Fatal	COMIRNATY	Nicotine dependence(H)	Cardiac arrest
Review Period	Initial	[redacted]	NETHERLANDS	Male	9-Mar-22	.	84	094F21ABS	[redacted]	Fatal		COMIRNATY; COMIRNATY	Cerebral haemorrhage
Review Period	Initial	[redacted]	UNITED KINGDOM	Male	########	########	31		[redacted]	Fatal			Abnormal loss of weight, Asthenia, Death, Decreased appetite, Dizziness, Dyspnoea, Fatigue, Lethargy, Nausea, Pain in extremity, Vomiting
Review Period	Initial	[redacted]	GERMANY	Female	########	.	93		[redacted]	Fatal		COMIRNATY; COMIRNATY	Acute myocardial infarction, Atrioventricular block, Cardiogenic shock
Review Period	Initial	[redacted]	NORTHERN IRELAND	Male	########	.	48	000014A	[redacted]	Fatal	COVID-19 VACCINE ASTRAZENECA; COVID-19 VACCINE ASTRAZENECA	Learning disability(H); Coloboma(H)	Circulatory collapse, Death, Dysarthria, Malaise
Review Period	Initial	[redacted]	LUXEMBOURG	Female	########	.	79	017G21A	[redacted]	Fatal		Cataract operation; Hypothyroidism(C); Hypertension(C); Pain(C); Type 2 diabetes mellitus(C); Gastrooesophageal reflux disease(H); Thyroidectomy(H); Breast cancer(H); COVID-19 VACCINE JANSSEN	COVID-19 immunisation, Diabetes mellitus inadequate control, Feeling abnormal, Pulmonary embolism
Review Period	Initial	[redacted]	NETHERLANDS	Male	########	.	76	018J21ABS	[redacted]	Fatal	SEMINIET	Arrhythmia(H); PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE	Arrhythmia, Cardiac arrest, Paraesthesia
Review Period	Initial	[redacted]	JAPAN	Male	########	.	87		[redacted]	Fatal		COMIRNATY; COMIRNATY	Drowning
Review Period	Initial	[redacted]	JAPAN	Male	########	7-Apr-22	76	000005A	[redacted]	Fatal	BAYASPIRIN; LANSOPRAZOLE; MAGNESIUM OXIDE; BELSOMRA; TRAZODONE HYDROCHLORIDE	Myocardial infarction(H); Chronic myeloid leukaemia(C); Hypothyroidism(H); Hyperuricaemia(H); Anaemia(H); Gastrooesophageal reflux disease(C); Constipation(C); Insomnia(C); Thrombocytosis(C); COMIRNATY; Comirnaty; Thyradin(H)	Arrhythmia
Review Period	Initial	[redacted]	GERMANY	Female	########	.	87		[redacted]	Fatal		COMIRNATY; COMIRNATY; COMIRNATY	Death, Deep vein thrombosis, Pulmonary embolism

RP	Initial_Follow_up	Case_ID	Country	Patient_Gender	Initial_Receipt_Date	Last_Report_Receipt_Date	Patient_Age__Years_	Batch_Lot_Number	WW_Identifier	Event_Outcome	Concomitant_Medications	Medical_History	ALL_PTs
Review Period	Initial	[redacted]	JAPAN	Female	########	5-Apr-22	87		[redacted]	Fatal	EDIROL; NORVASC; LOCHOLES; CELECOX; ARICEPT	Hypertension(C); Dementia Alzheimer's type(C); COMIRNATY; COMIRNATY; Dyslipidaemia(C); Osteoporosis(C); Back pain(C)	Cardio-respiratory arrest, Pneumonia, Sepsis
Review Period	Initial		TAIWAN, PROVINCE OF CHINA	Female	########	########	89			Fatal		Osteoporosis(H); ASTRAZENECA COVID-19 VACCINE; ASTRAZENECA COVID-19 VACCINE	Asthma, Fatigue, Somnolence
Review Period	Initial		TAIWAN, PROVINCE OF CHINA	Male	########	########	55			Fatal		Diabetes mellitus(C); COVID-19 VACCINE ASTRAZENECA; COVID-19 VACCINE ASTRAZENECA	Fatigue, Pain in extremity, Pyrexia, Vaccination site pain
Review Period	Initial		NORWAY	Male	########	########	78	3004498		Fatal			Cardiac arrest, COVID-19 immunisation, Pulmonary embolism
Review Period	Initial		JAPAN	Female	########	.	71			Fatal	EQUMET; AMLODIPINE; CIMETIDINE; LANDSEN; MIRTAZAPINE; BROTIZOLAM; BIPERIDEN HYDROCHLORIDE; ABILIFY	Dysaesthesia(C); Diabetes mellitus(C); Hypertension(C); COMIRNATY; COMIRNATY	Blood disorder, Cardio-respiratory arrest, Fracture, Internal haemorrhage, Loss of consciousness, Pain, Peripheral swelling
Review Period	Initial		GERMANY	Female	########	.	.			Fatal		COMIRNATY; COMIRNATY	Death, Hypersensitivity
Review Period	Initial		NETHERLANDS	Male	########	.	0			Fatal		Ex-tobacco user(H); PFIZER BIONTECH COVID-19 VACCINE; COVID-19 VACCINE	Abdominal pain, Haematemesis, Nausea
Review Period	Initial		UNITED KINGDOM	Female	########	########	57			Fatal	RELVAR ELLIPTA [FLUTICASONE FUROATE;VILANTEROL TRIFENATATE]; INCRUSE ELLIPTA; ZIMOVANE; SONDATE XL; ATORVASTATIN; CARBOCISTEINE; PREGABALIN; DIAZEPAM; MIRTAZAPINE; VITAMIN D NOS; GLYCERYL TRINITRATE	Chronic obstructive pulmonary disease(H); Lower respiratory tract infection(H); Bipolar disorder(H); Dissociative disorder(H); COVID-19 VACCINE ASTRAZENECA; COVID-19 VACCINE ASTRAZENECA	Asthenia, Cardiopulmonary failure, Contusion, Epistaxis, Facial paralysis, Fall, Pain in extremity, Respiratory tract infection, Yellow skin
Review Period	Initial		JAPAN	Female	########	.	73	000028A		Fatal	BUFFERIN C2; CILOSTAZOL; INSULIN	Chronic kidney disease(C); Haemodialysis(H); Diabetes mellitus(C); Comirnaty(H); Comirnaty(H)	Blood pressure decreased, Cerebral infarction, Death, Depressed level of consciousness, Pyrexia
Review Period	Initial		AUSTRIA	Male	########	########	67	3004670		Fatal		Pulmonary embolism(H); Hypertension(C); COMIRNATY; COMIRNATY; Cardiac hypertrophy(C); Hepatic steatosis(C); Anxiety disorder(C); Cardiomegaly(C); Hypertension(C)	Cardiac failure acute, COVID-19 immunisation
Review Period	Initial		JAPAN	Male	########	########	74	3005787		Fatal		COMIRNATY; COMIRNATY; Diabetes mellitus(C); Dyslipidaemia(C); Benign prostatic hyperplasia(C)	Arrhythmia, Cardio-respiratory arrest, Headache, Malaise, Myocardial infarction, Near drowning
Review Period	Initial		FRANCE	Female	########	.	62	214029		Fatal	HYDROCHLOROTHIAZIDE; AMLOR; METFORMINE [METFORMIN]; PARIET; CANDESARTAN CILEXETIL	Obesity(C); Type 2 diabetes mellitus(C); Hypertension(C); Breast injury(H); COMIRNATY; COMIRNATY	Carotid artery thrombosis, Ischaemic stroke
Review Period	Initial		JAPAN	Male	########	########	76	3005786		Fatal		Cerebral infarction(C); Diabetes mellitus(C); Cerebral infarction(H); COMIRNATY; COMIRNATY	Death, Depressed level of consciousness
Review Period	Initial		JAPAN	Female	########	########	83	000025A		Fatal	SEIBULE; METGLUCO; TRADIANCE; MICAMLO; AMLODIPINE; YOKUKANSAN	Diabetes mellitus(C); Hypertension(C); Dementia(C); Aortic valve stenosis(C); Delirium(H); COMIRNATY; COMIRNATY	Death, Loss of consciousness
Review Period	Initial		GERMANY	Female	########	.	77	000087A		Fatal		Granulomatosis with polyangiitis(C); COMIRNATY; COMIRNATY	Granulomatosis with polyangiitis
Review Period	Initial		ITALY	Male	########	########	80	000030A		Fatal		COMIRNATY; COMIRNATY	Ataxia, Confusional state, Dysphagia, Dystonia, Hallucination, Myoclonus, Nervous system disorder, Prion disease, Psychomotor hyperactivity, Respiratory failure, Sopor
Review Period	Initial		GERMANY	Male	5-Apr-22	.	49	000136A		Fatal		COMIRNATY; COMIRNATY	Coagulopathy, Endocarditis, Septic cerebral embolism, Staphylococcal sepsis, Thrombocytopenia
Review Period	Initial		GERMANY	Male	5-Apr-22	.	.	214008		Fatal		COMIRNATY	Pulmonary embolism
Review Period	Initial		GERMANY	Female	5-Apr-22	.	91	000125A		Fatal		COMIRNATY; COMIRNATY	Cerebral haemorrhage
Review Period	Initial		GERMANY	Male	6-Apr-22	.	62	000112A		Fatal		Type 2 diabetes mellitus(C); Hypertension(C); Autism spectrum disorder(C); Stent placement; VAXZEVRIA; COMIRNATY	Arrhythmia, Cardiac arrest
Review Period	Initial		NETHERLANDS	Female	6-Apr-22	.	86	018J21A		Fatal		COVID-19 VACCINE; COVID-19 VACCINE	Death, Thrombosis
Review Period	Initial		NETHERLANDS	Female	8-Apr-22	########	78	000060ABS		Fatal	CLOPIDOGREL; CANDESARTAN; ROSUVASTATINE CF	Endometrial cancer(C); PFIZER BIONTECH COVID-19 VACCINE; SPIKEVAX; Cerebrovascular accident(H); COVID-19(H)	Headache, Hypoxia, Pyrexia

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Review Period	Initial	[redacted]	JAPAN	Female	########	########	64	000207A	[redacted]	Fatal	DAIKENCHUTO; MOSAPRIDE CITRATE; TAKECAB; TELMISARTAN; THYRADIN S; SENNOSIDE A+B; BELSOMRA; TRAZODONE HYDROCHLORIDE; CALTAN; NIFEDIPINE	Haemodialysis; Aortic valve stenosis(C); Food allergy; Encapsulating peritoneal sclerosis(H); Chronic kidney disease(C); COMIRNATY; COMIRNATY; LEVOFLOXACIN HYDRATE(H); LOXOPROFEN SODIUM HYDRATE(H)	Aortic dissection rupture, Sudden death
Review Period	Initial	[redacted]	FRANCE	Male	########	.	51	079F21A	[redacted]	Fatal	COMIRNATY		Sudden death
Review Period	Initial	[redacted]	NETHERLANDS	Female	########	########	.	216036	[redacted]	Fatal		Delirium(H); Surgery; Dementia Alzheimer's type(C); COMIRNATY; COMIRNATY	Apathy, Hypophagia, Hyporesponsive to stimuli
Review Period	Initial	[redacted]	UNITED KINGDOM	Female	########	########	83	000076A	[redacted]	Fatal	ALLOPURINOL; ATENOLOL; DONEPEZIL; FLUOXETINE; LANSOPRAZOLE; MEMANTINE; MIRTAZAPINE; SENNA [SENNA ALEXANDRINA]; SIMVASTATIN; PARACETAMOL	Neoplasm(C); Chemotherapy; Hypertension(C); Squamous cell carcinoma(C); Gastrointestinal neoplasm(C); SARS-COV-2 VACCINE(H); SARS-COV-2 VACCINE(H); SARS-COV-2 VACCINE(H); Radiotherapy; Benign pleural neoplasm(C)	Death
Review Period	Initial	[redacted]	GERMANY	Male	########	.	86	000114A	[redacted]	Fatal		Chronic obstructive pulmonary disease(C); Hypertension(C); Tricuspid valve incompetence(C); Cardiac failure(C); Cardiac failure(C); Urinary incontinence(C); Dyspnoea exertional(C); Hypoxia(C); Atrial fibrillation(C); COMIRNATY; COMIRNATY	Cardiac failure
Review Period	Initial	[redacted]	JAPAN	Male	########	########	29		[redacted]	Fatal		COMIRNATY; COMIRNATY	Arrhythmia, Hepatic steatosis, Pyrexia
Review Period	Initial	[redacted]	GERMANY	Female	########	.	72	21046	[redacted]	Fatal		Cardiac failure(H); Supraventricular extrasystoles(H); Type 2 diabetes mellitus(C); Hypertension(C); Guillain-Barre syndrome(C); Diaphragmatic paralysis(H); COMIRNATY; COMIRNATY	Acute myocardial infarction, Dyspnoea, Malaise, Ventricular fibrillation
Review Period	Initial	[redacted]	NETHERLANDS	Male	########	########	62		[redacted]	Fatal	METFORMINE [METFORMIN]; AMLODIPINE	Type 2 diabetes mellitus(C); Diverticulitis(H); Incision site haemorrhage(H); Haemorrhoids thrombosed(H); Rectal haemorrhage(H); Hypertension(C); COVID-19 VACCINE ASTRAZENECA; COVID-19 VACCINE ASTRAZENECA	Mesenteric vein thrombosis, Portal vein thrombosis, Thrombocytopenia
Review Period	Initial	[redacted]	PHILIPPINES	Male	########	.	68		[redacted]	Fatal			Acute myocardial infarction, COVID-19
Review Period	Initial	[redacted]	UNITED KINGDOM	Female	1-May-22	########	89	000075A	[redacted]	Fatal	COMIRNATY; NITROFURANTOIN	Dementia Alzheimer's type(C); Asthenia(C)	Death
Review Period	Initial	[redacted]	GERMANY	Female	2-May-22	.	40		[redacted]	Fatal		Benign breast neoplasm(C); Seasonal allergy; Goitre(C); Neurodermatitis(C); COMIRNATY; COMIRNATY; Pulmonary haemorrhage(C)	Eczema, Hypersensitivity, Pruritus, Pulmonary haemorrhage, Pulmonary mass
Review Period	Initial	[redacted]	NETHERLANDS	Female	2-May-22	9-May-22	86		[redacted]	Fatal	OMEPRAZOL [OMEPRAZOLE]; CARBASALAATCALCIUM; HYDROCHLOORTHIAZIDE; LOSARTAN TEVA; BUDESONIDE AND FORMOTEROL; AMLODIPINE; ATORVASTATINE [ATORVASTATIN]; BISOPROLOL FUMARATE; AZITROMYCINE; METFORMIN [METFORMIN HYDROCHLORIDE]	Myocardial infarction(H); Granulomatosis with polyangiitis(H); Chronic obstructive pulmonary disease(H); Coronary artery disease(H); COVID-19 VACCINE; COVID-19 VACCINE; COVID-19 VACCINE	Condition aggravated, Cough, Dyspnoea, Granulomatosis with polyangiitis, Haemoptysis
Review Period	Initial	[redacted]	GERMANY	Female	4-May-22	.	38	000114A	[redacted]	Fatal		COVID-19 VACCINE JANSSEN; SPIKEVAX	Pulmonary embolism
Review Period	Initial	[redacted]	FRANCE	Female	4-May-22	.	78		[redacted]	Fatal	ACIDE FOLIQUE; SALBUTAMOL; BISOPROLOL LPH; ATORVASTATINE EG; METHOTREXATE; SOLUPRED ORO; CHLORHYDRATE DE PROCAINE	Cardiac hypertrophy(H); Hysterectomy; Enlarged clitoris(H); Type 2 diabetes mellitus(C); Rheumatoid arthritis(C); Respiratory failure(H); Congenital absence of bile ducts(C); Breast mass(H); Vulvectomy; Hypertension(C); Obesity(H); Dyslipidaemia(H)	COVID-19 pneumonia, Vaccination failure
Review Period	Initial	[redacted]	TAIWAN, PROVINCE OF CHINA	Female	########	.	51		[redacted]	Fatal		BNT162B2; BNT162B2	Headache, Nausea, Vomiting

RP	Initial_Follow_up	Case_ID	Country	Patient_Gender	Initial_Receipt_Date	Last_Report_Receipt_Date	Patient_Age__Years_	Batch_Lot_Number	WW_Identifier	Event_Outcome	Concomitant_Medications	Medical_History	ALL_PTs
Review Period	Initial	[redacted]	GERMANY	Male	5-May-22	1-Jun-22	51		[redacted]	Fatal		COVID-19 VACCINE; Cardiac hypertrophy(H); Tobacco abuse(H)	Brain oedema, Cardiac failure acute, Endocarditis, Influenza like illness, Myocarditis
Review Period	Initial		JAPAN	Male	2-May-22	1-Jun-22	65	3006278		Fatal		Mitral valve repair; Hypertension(C); COMIRNATY; COMIRNATY	Apnoea, Cardiac hypertrophy, Cardio-respiratory arrest, Chills, Feeling hot, Incontinence, Malaise, Muscular weakness, Pain, Pyrexia
Review Period	Initial		TAIWAN, PROVINCE OF CHINA	Male	########	.	34			Fatal		ASTRAZENECA COVID-19 VACCINE; ASTRAZENECA COVID-19 VACCINE; ASTRAZENECA COVID-19 VACCINE	Pyrexia, Vaccination site pain
Review Period	Initial		TAIWAN, PROVINCE OF CHINA	Female	########	.	62			Fatal		Pulmonary fibrosis(C); ASTRAZENECA COVID-19 VACCINE	Headache, Muscular weakness
Review Period	Initial		SWEDEN	Female	6-May-22	.	94	016G21A		Fatal		Upper limb fracture(H); Drug hypersensitivity; Colon cancer(H); Angina pectoris(C); Diarrhoea(H)	Cardiac arrest, COVID-19 immunisation, Decreased appetite, Fatigue, General physical health deterioration, Malnutrition, Mobility decreased, Multiple organ dysfunction syndrome, Personality change
Review Period	Initial		GERMANY	Female	9-May-22	.	88	092F21A		Fatal		Depression(H); Polyneuropathy(C); Hyperlipidaemia(C); Hypertension(C)	Aspiration, Asthenia, Atonic seizures, Dementia Alzheimer's type, Dysarthria, Dysphagia, Dyspnoea, Palliative care, Quadriplegia
Review Period	Initial		PHILIPPINES	Female	#########	.	39	068F21A		Fatal			Death
Review Period	Initial		PHILIPPINES	Female	#########	.	53	061G21A		Fatal			Death
Review Period	Initial		JAPAN	Male	########	.	74			Fatal		Cardiac failure(C); Chronic kidney disease(C); Carotid arteriosclerosis(C); Hypertension(C); Diabetes mellitus(C); Dyslipidaemia(C); Constipation(C); Gastric ulcer haemorrhage(C); COMIRNATY; COMIRNATY(H)	Blood pressure decreased, Bradycardia, Cardio-respiratory arrest, Chest discomfort, Depressed level of consciousness, Mydriasis, Oxygen saturation decreased, Restlessness, Sudden cardiac death
Review Period	Initial		GERMANY	Male	#########	6-Jun-22	60			Fatal		COMIRNATY	Abdominal pain upper, Cerebrovascular accident, Colon cancer
Review Period	Initial		NETHERLANDS	Female	########	1-Jun-22	69			Fatal	CLOPIDOGREL TEV; LISINOPRIL/HYDROCHLOORTHIAZIDE; QUETIAPINE GH; CALCIUMCARBONAAT; ATORVASTATINE EG; APO-BECLOMETHASONE; PANTOPRAZOLO	Diverticulitis(H); Hypothyroidism(H); Chronic obstructive pulmonary disease(C); Polyarthritis(C); Blood cholesterol increased(C); Hypertension(C); Polymyalgia rheumatica(H); Type 2 diabetes mellitus(H); Cerebrovascular accident(H); Gastric bypass(H); Joint prosthesis user(C); Lichen sclerosus(H); MODERNA COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE(H)	Circulatory collapse, Diarrhoea, Ear haemorrhage, Haematoma, Influenza like illness, Insomnia, Limb discomfort, Malaise, Nausea, Oedema peripheral, Resuscitation
Review Period	Initial		JAPAN	Male	#########	#########	64	000049A		Fatal		Colitis ischaemic(C); Hypertension(H); Hyperuricaemia(H); COMIRNATY; COMIRNATY	Arteritis coronary, Circulatory collapse, Coronary artery stenosis, Dehydration, Myocarditis
Review Period	Initial		UNITED KINGDOM	Female	#########	9-Jun-22	90			Fatal		Heavy menstrual bleeding(H); Hyperparathyroidism(H); Blood pressure fluctuation(H); Syncope(H); Eyelid rash(H); Sarcoma(H); Femur fracture(H); Depression(C); Arthritis(C); Anxiety(C)	Agitation, Agonal respiration, Cardiac arrest, Choking, Confusional state, Delirium, Fall, Hypotension, Malaise, Personality change, Productive cough, Psychomotor hyperactivity, Seizure
Review Period	Initial		ITALY	Male	#########	#########	76	3005884 sc 0		Fatal	CARDIOASPIRIN; TICAGRELOR; NOVORAPID; PANTOPRAZOLE; XIGDUO; TOUJEO; ATORVASTATIN	Diabetes mellitus(C); Pulmonary hypertension(H); COMIRNATY; COMIRNATY	Syncope
Review Period	Initial		TAIWAN, PROVINCE OF CHINA	Female	9-May-22	.	29			Fatal		COVID-19 VACCINE MRNA (BNT162B2); COVID-19 VACCINE MRNA (BNT162B2); Hepatocellular carcinomaFH	Contusion, Eye pain, Headache, Vision blurred
Review Period	Initial		TAIWAN, PROVINCE OF CHINA	Male	9-May-22	.	59	2100686_111		Fatal		COVID-19 MRNA VACCINE BNT162B2	Coronary artery disease
Review Period	Initial		TAIWAN, PROVINCE OF CHINA	Male	9-May-22	.	55			Fatal		PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE	Death
Review Period	Initial		JAPAN	Female	#########	.	84			Fatal		Back pain(C); Hypertension(C); Dementia(C); COMIRNATY; COMIRNATY	Bacterial infection, Multiple organ dysfunction syndrome, Pneumonia, Pulmonary alveolar haemorrhage, Respiratory failure, Vasculitis
Review Period	Initial		UNITED STATES	Male	#########	.	75	065K21A; 03		Fatal	VENLAFAXINE; LORAZEPAM; MIDODRINE; TRAZODONE; MIRALAX; TYLENOL; VITAMIN D2; PREVACID; SEROQUEL	Alcohol use(H); Drug hypersensitivity; Non-tobacco user(C); Arterial stent insertion; Parkinson's disease(C)	Dementia, Interchange of vaccine products, Parkinson's disease, Pyrexia, Seizure

RP	Initial_Follow_up	Case_ID	Country	Patient_Gender	Initial_Receipt_Date	Last_Report_Receipt_Date	Patient_Age__Years_	Batch_Lot_Number	WW_Identifier	Event_Outcome	Concomitant_Medications	Medical_History	ALL_PTs
Review Period	Initial	[redacted]	UNITED KINGDOM	Male	########	.	98		[redacted]	Fatal	PARACETAMOL	Suspected COVID-19(H); SARS-COV-2 VACCINE(H); SARS-COV-2 VACCINE; SARS-COV-2 VACCINE	Abdominal pain, COVID-19, Death, Fatigue, Thirst, Vomiting
Review Period	Initial		UNITED KINGDOM	Male	########	1-Jun-22	82	000018A		Fatal	BENFERIDOL; BISOPROLOL; GLICLAZIDE; LINAGLIPTIN; MIRTAZAPINE	Living in residential institution(H); Hypertension(C); Vascular dementia(C); Atrial fibrillation(C); Type 2 diabetes mellitus(C); Chronic kidney disease(C); SARS-COV-2 VACCINE; SARS-COV-2 VACCINE; SARS-COV-2 VACCINE	Pneumonia
Review Period	Initial		JAPAN	Male	########	.	82			Fatal		Interstitial lung disease(C); Pulmonary fibrosis(C); COMIRNATY; COMIRNATY	Pulmonary alveolar haemorrhage, Respiratory failure, Vasculitis
Review Period	Initial		GERMANY	Male	########	.	60			Fatal		COMIRNATY; COMIRNATY	Cerebrovascular accident, Colon cancer
Review Period	Initial		NETHERLANDS	Male	########	27-Jun-22	80	3005789BS		Fatal	SEMINIET	PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE; Hypertension(C); Bronchitis(C)	Arrhythmia, Chills, Febrile convulsion, Hypoxia, Pneumonia, Pulmonary embolism, Pyrexia, Sepsis
Review Period	Initial		ITALY	Female	########	.	89	214024 sc 09		Fatal		COMIRNATY; COMIRNATY	Dyspnoea, Non-small cell lung cancer, Pleural effusion
Review Period	Initial		TAIWAN, PROVINCE OF CHINA	Male	########	.	81			Fatal		Hypertension(C); Dialysis; ASTRAZENECA COVID-19 VACCINE; ASTRAZENECA COVID-19 VACCINE	Death
Review Period	Initial		TAIWAN, PROVINCE OF CHINA	Male	########	.	63			Fatal		ASTRAZENECA COVID-19 VACCINE; ASTRAZENECA COVID-19 VACCINE	Hypoaesthesia, Pyrexia
Review Period	Initial		TAIWAN, PROVINCE OF CHINA	Male	########	.	50	048M21A_1		Fatal		BNT162B2; BNT162B2	Pneumonia
Review Period	Initial		TAIWAN, PROVINCE OF CHINA	Male	########	.	43			Fatal		Mitral valve prolapse(H); Ventricular hypertrophy(H); COVID-19 MRNA VACCINE BNT162B2; COVID-19 MRNA VACCINE BNT162B2; Tobacco user(C); Catheterisation cardiac	Cardiogenic shock
Review Period	Initial		TAIWAN, PROVINCE OF CHINA	Female	########	.	59			Fatal		Diabetes mellitus(C); Cellulitis(H); Dialysis; ASTRAZENECA COVID-19 VACCINE	Death
Review Period	Initial		TAIWAN, PROVINCE OF CHINA	Female	########	.	80	2100696_111		Fatal		Dialysis; COVID-19 VACCINE ASTRAZENECA; COVID-19 VACCINE ASTRAZENECA	Death
Review Period	Initial		SPAIN	Male	########	.	77	3001532; 300		Fatal		Retinopathy hypertensive(H); Atrial fibrillation(H); Type 2 diabetes mellitus(H); Chronic kidney disease(H); Hypertension(H); Cerebrovascular accident(H); Dyslipidaemia(H)	COVID-19 immunisation, COVID-19 pneumonia, Vaccination failure
Review Period	Initial		UNITED STATES	Female	1-Jun-22	.	.			Fatal			Haemorrhage, Interchange of vaccine products, Myocardial infarction, Thrombosis
Review Period	Initial		GERMANY	Female	3-Jun-22	13-Jun-22	31			Fatal		JANSSEN COVID-19 VACCINE	Cardiomyopathy, Death, Microangiopathy
Review Period	Initial		PHILIPPINES	Female	2-Jun-22	.	81			Fatal			Asthenia, COVID-19, Dyspnoea
Review Period	Initial		PHILIPPINES	Male	2-Jun-22	.	59	939900		Fatal			Acute respiratory distress syndrome, Asthenia, Decreased appetite, Vision blurred
Review Period	Initial		GERMANY	Female	7-Jun-22	.	66	1401		Fatal		COMIRNATY; COMIRNATY	Myocardial infarction
Review Period	Initial		FRANCE	Female	7-Jun-22	.	96	214005		Fatal	CORDARONE; FLUIDABAK; LOXENIL; PLAVIX; DOLIPRANE; COLECALCIFEROL; ATARAXOID; PANTOPRAZOLE; VOGALENE; TIMOLOLO; CALCIUM IPODATE; BRINZOLAMIDE; VOLTARENE LP; COLECALCIFEROL; NORSET	Atrial fibrillation(H); Gastric ulcer(H); Dyslipidaemia(H); Cerebrovascular accident(H); Hypertension(H); Age-related macular degeneration(H); Cardiac failure(H); Femur fracture(H); Cataract(H); Gastrointestinal haemorrhage(H)	COVID-19 pneumonia, Vaccination failure
Review Period	Initial		GERMANY	Female	9-Jun-22	.	88	092F21A		Fatal		COMIRNATY; COMIRNATY	Bone cancer
Review Period	Initial		TAIWAN, PROVINCE OF CHINA	Male	6-Jun-22	.	50	048M21A_1		Fatal		ASTRAZENECA COVID-19 VACCINE; ASTRAZENECA COVID-19 VACCINE	Death, Discomfort, Dizziness
Review Period	Initial		PHILIPPINES	Female	9-Jun-22	.	45	939900; 056I		Fatal			Malaise

RP	Initial_ Follow_ up	Case_ID	Country	Patient_Gend er	Initial_Recei pt_Date	Last_Report_R eceipt_Date	Patient _Age__ Years_	Batch_Lot_ Number	WW_Identifier	Event_Outcome	Concomitant_Medications	Medical_History	ALL_PTs
Review Period	Initial	[redacted]	FRANCE	Male	14-Jun-22	.	75	057G21A	[redacted]	Fatal	COMIRNATY	Cerebrovascular accident(H); Carotid arteriosclerosis(H); Hypertension(H)	Acute pulmonary oedema
Review Period	Initial	[redacted]	GERMANY	Male	16-Jun-22	.	67	3004951	[redacted]	Fatal		Hypothyroidism(C); COMIRNATY; COMIRNATY	Death
Review Period	Initial	[redacted]	UNITED KINGDOM	Male	16-Jun-22	.	.	000088A	[redacted]	Fatal	PFIZER BIONTECH COVID-19 VACCINE	Chronic lymphocytic leukaemia(H)	Death

Case ID	WW Identifier	Narrative Complete
[redacted]	[redacted]	This case was initially received via [redacted] (Reference number: [redacted]) on 02-Jan-2022. The most recent information was received on 14-Jan-2022 and was forwarded to Moderna on 14-Jan-2022. .This regulatory authority case was reported by a physician and describes the occurrence of FOETAL EXPOSURE DURING PREGNANCY (Foetal exposure during pregnancy) and STILLBIRTH (Stillbirth NOS) in a patient of an unknown age and gender exposed to mRNA-1273 (Moderna CoviD-19 Vaccine) , while the mother received the product for COVID-19 vaccination. . .MEDICAL HISTORY (Parent): The mother's past medical history included Pregnancy (Estimated due date: 20220128), Body mass index (Normal), Pregnancy (3 previous pregnancies. All normal births), Glucose tolerance test (Normal), Blood pressure (Normal) and COVID-19 virus test (No - Negative COVID-19 test)..Previously administered products included for COVID-19 vaccination: COVID-19 VACCINE ASTRAZENECA on 16-Jul-2021..Past adverse reactions to the above products included No adverse event with COVID-19 VACCINE ASTRAZENECA.. .MEDICAL HISTORY (Patient): Concomitant product exposures included FOLIC ACID for Folic acid supplementation.. ..In December 2021, the mother received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. The mother's last menstrual period was on an unknown date and the estimated date of delivery was 18-Jan-2022. On 30-Dec-2021, the patient was diagnosed with FOETAL EXPOSURE DURING PREGNANCY (Foetal exposure during pregnancy) (seriousness criteria death, hospitalization, medically significant and congenital anomaly). 30-Dec-2021, the patient experienced STILLBIRTH (Stillbirth NOS) (seriousness criteria death, hospitalization, medically significant and congenital anomaly). The patient was exposed to mRNA-1273 (Moderna CoviD-19 Vaccine) beginning around the first trimester of the pregnancy..The delivery occurred on 30-Dec-2021, which was reported as Still birth..For foetus 1, The outcome was reported as Stillbirth w Congenital Anomaly. An autopsy was not performed. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On an unknown date, Scan: normal (normal) Normal growth on scans and normal (normal) Normal anomaly scan.. . .For mRNA-1273 (Moderna CoviD-19 Vaccine) (Transplacental), the reporter did not provide any causality assessments.. .Attended hospital due to absent foetal movements. Baby found to have no heartbeat. No other abnormalities on scan. No other maternal illness. Mother has normal body mass index (BMI), no hypertension. Being induced from today for stillbirth. Details of previous pregnancies: 3 previous pregnancies. All normal births. 1st baby had cardiac abnormality which was successfully surgically treated postnatally. Fit and well in previous pregnancies..Patient was exposed to the medicine first-trimester (1-12 weeks)..Company Comment: This regulatory case concerns a still born baby, whose mother is 42-year-old with relevant medical history of concomitant administration of the AstraZeneca COVID-19 vaccine, exposure to 'the medicine' during the first trimester (1 to 12 weeks) of pregnancy and unspecified Cardiac abnormality of the first baby. who experienced unexpected serious events of Foetal exposure during pregnancy and Stillbirth. The mother received the third dose of the mRNA-1273 vaccine on an unspecified date in Dec2021. The event stillbirth occurred 29 days after administration of the third dose of mRNA-1273 vaccine. The patients mother had normal BMI and normal blood pressure and had normal Glucose Tolerance Test result. Details of investigations showed that the baby had normal growth and normal anomaly scan. However, on an unspecified date, the patients mother was admitted to the hospital due to absent fetal movements and the baby was found to have no heartbeat, she was then induced for stillbirth. The history of concomitant administration of the AstraZeneca COVID-19 vaccine, exposure to 'the medicine' during the first trimester of pregnancy and unspecified Cardiac abnormality of the first baby remain as confounders. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. The case was assessed as serious as per Regulatory Authority´s report due to important medical condition, hospitalization, congenital anomaly and fatal outcome(death).. .Most recent FOLLOW-UP information incorporated above includes:.On 14-Jan-2022: Significant follow-up document was received on 14-JAN-2022- Seriousness Criteria of case updated, Patient details, Parent details were updated, Patient route of administration was updated, Action taken, indication for suspect product was updated, events section updated.
[redacted]	[redacted]	This case was received via European Medicines Agency (Reference number: [redacted]) on 05-Jan-2022 and was forwarded to Moderna on 05-Jan-2022. ..This regulatory authority case was reported by a physician and describes the occurrence of LOSS OF CONSCIOUSNESS (Unconsciousness), ANGINA PECTORIS (Chest pain - cardiac), DYSPNOEA (Acute dyspnea), RESUSCITATION (Cardiopulmonary resuscitation) and INFLUENZA LIKE ILLNESS (Flu-like symptoms) in a 33-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 042G21A) for COVID-19 vaccination. . .Previously administered products included for COVID-19 vaccination: Comirnaty BNT162b2 on 27-Apr-2021 and Comirnaty BNT162b2 on 18-May-2021..Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Comirnaty BNT162b2..Concurrent medical conditions included Pollinosis...On 14-Dec-2021, the patient

Case ID	WW Identifier	Narrative Complete
		received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 15-Dec-2021, the patient experienced LOSS OF CONSCIOUSNESS (Unconsciousness) (seriousness criterion death), ANGINA PECTORIS (Chest pain - cardiac) (seriousness criterion death), DYSPNOEA (Acute dyspnea) (seriousness criterion death), RESUSCITATION (Cardiopulmonary resuscitation) (seriousness criterion death) and INFLUENZA LIKE ILLNESS (Flu-like symptoms) (seriousness criterion death). The patient died on 15-Dec-2021. The cause of death was not reported. An autopsy was performed, but no results were provided. . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .Concomitant medications was not provided by the reporter..Treatment information was not provided..Autopsy at the University Hospital Augsburg, result not known.Company comment.This case concerns a 33-year-old male patient, with medical history of Pollinosis, who experienced the unexpected serious fatal events of LOSS OF CONSCIOUSNESS, ANGINA PECTORIS, DYSPNOEA, RESUSCITATION and INFLUENZA LIKE ILLNESS. The events occurred on the following day of the administration of the third dose of mRNA-1273 vaccine. The patient died on 15-Dec-2021. The cause of death was not reported. An autopsy was performed, but no results were provided. Patient's medical history of Pollinosis, remains as a confounder. Patient had received Comirnaty BNT162b2 as previous COVID-19 vaccination, on 27-Apr-2021 and 18-May-2021. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 04-Jan-2022.
[redacted]	[redacted]	This case was received via European Medicines Agency (Reference number: [redacted]) on 05-Jan-2022 and was forwarded to Moderna on 05-Jan-2022. .This regulatory authority case was reported by a physician and describes the occurrence of CARDIOVASCULAR DISORDER (Cardiovascular disease, unspecified) and RESUSCITATION (Resuscitation) in a 60-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000114A) for COVID-19 vaccination. . .Previously administered products included for COVID-19 vaccination: COVID-19 Vaccine Janssen (COVID-19 Vaccine Janssen Injektionssuspension COVID-19 Vaccine JanssenCOVID-19-Impfstoff Ad26.COV2-S) in July 2021..Past adverse reactions to the above products included No adverse event with COVID-19 Vaccine Janssen.. ..On 18-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, the patient experienced CARDIOVASCULAR DISORDER (Cardiovascular disease, unspecified) (seriousness criterion death) and RESUSCITATION (Resuscitation) (seriousness criterion death). The cause of death was not reported. It is unknown if an autopsy was performed. . . .The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown.. .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .No concomitant and treatment information was provided..Date of death of patient is not communicated..Company comment.This case concerns a 60-year-old male patient, with no reported medical history, who experienced the unexpected serious fatal events of CARDIOVASCULAR DISORDER and RESUSCITATION. The patient received dose of mRNA-1273 vaccine on 18-Dec-2021. Date of death of patient was not communicated. The cause of death was not reported. It is unknown if an autopsy was performed. Patient had received COVID-19 Vaccine Janssen as previous vaccination, in July 2021. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 04-Jan-2022.
[redacted]	[redacted]	This case was initially received via United Kingdom MHRA (Reference number: [redacted]) on 05-Jan-2022. The most recent information was received on 06-Feb-2022 and was forwarded to Moderna on 06-Feb-2022. .This regulatory authority case was reported by a consumer and describes the occurrence of PULMONARY THROMBOSIS (pulmonary thrombosis), TRANSIENT ISCHAEMIC ATTACK (TIA), DEEP VEIN THROMBOSIS (DVT), CARDIAC ARREST (Cardiac arrest), HAEMATOCHEZIA (Blood in stool) and PAIN IN EXTREMITY (Leg pain) in a 63-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3004675) for COVID-19 vaccination. . .The patient's past medical history included Steroid therapy (Taking regular steroid treatment (e.g. orally or rectally)) and Colostomy..Concurrent medical conditions included Vascular dementia (Treatment for Vascular Dementia)..Concomitant products included COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) from 24-Feb-2021 to 19-May-2021 and COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) from 24-Feb-2021 to an unknown date for COVID-19 vaccination, MEMANTINE and DONEPEZIL HYDROCHLORIDE for Vascular dementia, ASPIRIN [ACETYLSALICYLIC ACID], CETIRIZINE HYDROCHLORIDE,

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		LISINOPRIL and LEVOTHYROXINE for an unknown indication.. ..On 24-Nov-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 15-Nov-2021, the patient experienced HAEMATOCHEZIA (Blood in stool) (seriousness criteria hospitalization, disability and medically significant) and PAIN IN EXTREMITY (Leg pain) (seriousness criteria hospitalization, disability and medically significant). On 25-Nov-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced TRANSIENT ISCHAEMIC ATTACK (TIA) (seriousness criteria hospitalization, disability and medically significant). On 15-Dec-2021, the patient experienced DEEP VEIN THROMBOSIS (DVT) (seriousness criteria hospitalization, disability and medically significant). On an unknown date, the patient experienced PULMONARY THROMBOSIS (pulmonary thrombosis) (seriousness criteria hospitalization, disability and medically significant) and CARDIAC ARREST (Cardiac arrest) (seriousness criteria death, hospitalization, disability and medically significant). On 29-Nov-2021, TRANSIENT ISCHAEMIC ATTACK (TIA) had resolved. The patient died on 15-Dec-2021. The reported cause of death was Cardiac arrest. An autopsy was performed. The autopsy-determined cause of death was Pulmonary thromboembolism and Thrombosis venous deep. At the time of death, PULMONARY THROMBOSIS (pulmonary thrombosis), DEEP VEIN THROMBOSIS (DVT), HAEMATOCHEZIA (Blood in stool) and PAIN IN EXTREMITY (Leg pain) had not resolved. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On an unknown date, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test..On an unknown date, Scan: not reported not reported and not reported not reported.. . . .Patient not had symptoms associated with COVID-19. Hospital said TIA but second scan showed different. Patient died 10 days later from deep vein thrombosis (DVT) clot and pulmonary thrombosis (heart attack). Patient had not tested positive for COVID-19 since had the vaccine...Company Comment: This is a regulatory case concerning a 63 year-old, female patient with a history of vascular dementia, polypharmacy and Interchange of vaccine products (vaccination with two doses of COVID-19 vaccine AstraZeneca approximately 6 months prior), who experienced the serious Fatal unexpected, event of cardiac arrest and the serious unexpected AESI of Pulmonary thrombosis, Transient ischaemic attack and Deep vein thrombosis. The event Transient ischaemic attack occurred approximately 1 day after the booster dose of mRNA-1273 vaccine, the patient was admitted to the hospital and was after discharged, the event was reported as recovered. The events Deep vein thrombosis and cardiac arrest occurred approximately 21 days after the booster dose of mRNA-1273 vaccine (the day the patient died) and the event Pulmonary thrombosis on an unknown date. The rechallenge was not applicable due to the fatal outcome. The patient died 21 days after receiving the booster dose of mRNA-1273 vaccine, the reported cause of death by the regulatory authority was cardiac arrest, it is unknown whether an autopsy was performed. The reporter states that the death certificate provides as causes of death Pulmonary thrombosis, and Deep vein thrombosis. The medical history, of vascular dementia and polypharmacy suggests unreported, unspecified cardiovascular disorder which could remain as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 06-Feb-2022: Follow-up Received - Medical history (Colostomy) added, relevant history updated, Lab test (Scan) added, Autopsy result added, Dose details added for concomitant drug, event (Pain in extremity, Haematochezia) added.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 05-Jan-2022 and was forwarded to Moderna on 05-Jan-2022. .This regulatory authority case was reported by a physician and describes the occurrence of ARRHYTHMIA (Cardiac arrhythmia/cardiac arrest) and CARDIAC ARREST (Cardiac arrhythmia/cardiac arrest) in a 63-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 093F21A) for COVID-19 vaccination. . .Previously administered products included for Product used for unknown indication: AstraZeneca vaccin (Vaxzevria) COVID-19 VACCIN ASTRAZENECA INJVLST on 10-Mar-2021 and AstraZeneca vaccin (Vaxzevria) COVID-19 VACCIN ASTRAZENECA INJVLST on 26-May-2021..Past adverse reactions to the above products included No adverse event with AstraZeneca vaccin (Vaxzevria) COVID-19 VACCIN ASTRAZENECA INJVLST and AstraZeneca vaccin (Vaxzevria) COVID-19 VACCIN ASTRAZENECA INJVLST.. ..On 17-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 18-Dec-2021, the patient experienced ARRHYTHMIA (Cardiac arrhythmia/cardiac arrest) (seriousness criteria death, medically significant and life threatening) and CARDIAC ARREST (Cardiac arrhythmia/cardiac arrest) (seriousness criteria death, medically significant and life threatening). The reported cause of death was brain damage after 8x aed blows and Arrhythmia. It is unknown if an autopsy was performed. . . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .Concomitant medication use was unknown.Treatment information was unknown..Company Comment - This regulatory authority case concerns a 63 year old male patient with no relevant

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		medical history, who experienced the serious unexpected events of arrhythmia and cardiac arrest. The events occurred 1 day after a dose of mRNA-1273 vaccine, and had a fatal outcome with death occurring the same day. The reported cause of death was brain damage from AED blows and Arrhythmia. The rechallenge was not applicable. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 05-Jan-2022 and was forwarded to Moderna on 05-Jan-2022. .This regulatory authority case was reported by a physician and describes the occurrence of PULMONARY EMBOLISM (DD brilliant LAE), CARDIOVASCULAR SYMPTOM (DD cardiovascular complication) and CEREBROVASCULAR ACCIDENT (V.a. cerebraler Insult) in a male patient of an unknown age who received mRNA-1273 (Spikevax) (batch no. 3004951) for COVID-19 immunisation. . .Previously administered products included for Prophylactic vaccination: Comirnaty BNT162b2..Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2.. ..On 09-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, the patient experienced PULMONARY EMBOLISM (DD brilliant LAE) (seriousness criterion death), CARDIOVASCULAR SYMPTOM (DD cardiovascular complication) (seriousness criterion death) and CEREBROVASCULAR ACCIDENT (V.a. cerebraler Insult) (seriousness criterion death). The cause of death was not reported. An autopsy was performed, but no results were provided. . . .The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown.. .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .Concomitant medications was not provided by the reporter...Autopsy was pending due to primary vaccination with Comirnaty...Treatment information was not provided...Company comment: This is a regulatory case concerning a male patient of unknown age, with no reported medical history and Interchange of vaccine products (vaccination with primary series of COVID-19 vaccine BioNTech dates not provided), who experienced the serious Fatal unexpected, AESI of pulmonary embolism and Cerebrovascular accident; and the serious Fatal unexpected, event of Cardiovascular symptom. The events occurred on an unknown date after a dose of mRNA-1273 vaccine. The patient died on an unknown date, the cause of death was reported as unknown, an autopsy was performed and the report was pending. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
[redacted]		This case was initially received via United Kingdom MHRA (Reference number: [redacted] on 09-Jan-2022. The most recent information was received on 18-Jan-2022 and was forwarded to Moderna on 18-Jan-2022. .This regulatory authority case was reported by a pharmacist and describes the occurrence of ARRHYTHMIA (arrhythmia), the first episode of PALPITATIONS (Palpitations), ELECTROCARDIOGRAM ABNORMAL (Abnormal ECG), PAROXYSMAL ARRHYTHMIA (Paroxysmal arrhythmia), MYOCARDITIS (Myocarditis), CARDIOMYOPATHY (Cardiomyopathy), the second episode of PALPITATIONS (Palpitations) and DEATH (Death) in a 63-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3004732) for COVID-19 vaccination. . .The patient's past medical history included Dog bite on 10-Dec-2021..Concomitant products included COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) from 06-Mar-2021 to an unknown date and COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) from 18-May-2021 to an unknown date for COVID-19 vaccination.. ..On 11-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 29-Dec-2021, the patient experienced ELECTROCARDIOGRAM ABNORMAL (Abnormal ECG) (seriousness criterion medically significant). On an unknown date, the patient experienced ARRHYTHMIA (arrhythmia) (seriousness criterion medically significant), the first episode of PALPITATIONS (Palpitations) (seriousness criterion medically significant), PAROXYSMAL ARRHYTHMIA (Paroxysmal arrhythmia) (seriousness criterion medically significant), MYOCARDITIS (Myocarditis) (seriousness criterion medically significant), CARDIOMYOPATHY (Cardiomyopathy) (seriousness criterion medically significant) and the second episode of PALPITATIONS (Palpitations) (seriousness criterion medically significant). The patient died on 31-Dec-2021. The cause of death was not reported. An autopsy was not performed. At the time of death, ARRHYTHMIA (arrhythmia), ELECTROCARDIOGRAM ABNORMAL (Abnormal ECG), PAROXYSMAL ARRHYTHMIA (Paroxysmal arrhythmia), MYOCARDITIS (Myocarditis), CARDIOMYOPATHY (Cardiomyopathy) and the last episode of PALPITATIONS (Palpitations) outcome was unknown. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 29-Dec-2021, Chest X-ray: normal (normal) clear lung fields, no cardiomegaly..On 29-Dec-2021, Electrocardiogram: sinus rhythm, tw inversion leads iii, avf, v3-v6 (abnormal) sinus rhythm, TW inversion leads III, aVF, V3-V6..On 29-Dec-2021, Troponin (Unknown-41): normal (normal) normal..On 30-Dec-2021, Echocardiogram: normal (normal) bedside LV dimensions appear borderline dilated, no obvious RWMA, no obvious significant valve abnormalities.. . .For mRNA-

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		1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.. .test. COVID-19 infection status- no record on GP clinical system of any positive COVID tests..Local identification number: [redacted] Moderna 0.25mL booster dose was given.- Dec-2021, patient had GP consultation as palpitations over past month (about 5 episodes). No chest pain, SOB or obvious trigger. Sporadic- could go days without symptoms.Dec-2021, had abnormal ECG at GP Surgery. Admitted to hospital for overnight. Discharge letter states an unclear diagnosis- possible paroxysmal arrhythmia, possible resolving myocarditis, possible underlying cardiomyopathy. No treatment was stated on hospital discharge letter. Patient seen by a cardiologist.Initial ECG showed T wave inversion in anterior and antero-lateral leads. No arrhythmia during cardiac monitoring on CCU.On 31-Dec-2021, died in RTA (driver). Copy of the post-mortem report was not currently available..Company Comment: This regulatory case concerns a 63-year-old female patient with no relevant medical history, with an Interchange of vaccine products (two doses was with COVID-19 VACCINE ASTRAZENECA, 6 month 23 days before current vaccination), who experienced the unexpected serious AESI events of Arrhythmia, Paroxysmal Arrhythmia, Myocarditis and Cardiomyopathy, unexpected serious events of the first episode of Palpitations, Electrocardiogram Abnormal, the second episode of Palpitations and Death with a fatal outcome. The event of Electrocardiogram Abnormal occurred 18 days after the third dose of mRNA-1273 vaccine, while the events of Arrhythmia, Paroxysmal Arrhythmia, Cardiomyopathy, Myocarditis, the first episode of Palpitations, and the second episode of Palpitations occurred on an unspecified date after the third dose of mRNA-1273 vaccine. Patient died in RTA 20 days after the vaccination. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. ... .Most recent FOLLOW-UP information incorporated above includes:.On 18-Jan-2022: Follow-up received: Medical history, laboratory data, death date and cause of death, suspect product indication and action taken, concomitant medication indication, dose number and batch/lot number updated, new event of death and additional seriousness and I-narrative was updated.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 10-Jan-2022 and was forwarded to Moderna on 10-Jan-2022. .This regulatory authority case was reported by a physician and describes the occurrence of SUDDEN DEATH (Sudden death unexplained) and BREAST PAIN (Breast pain) in a 67-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. . .Previously administered products included for COVID-19: COVID-19 VACCINE ASTRAZENECA on 21-Apr-2021 and COMIRNATY on 14-Jul-2021..Past adverse reactions to the above products included No adverse event with COMIRNATY and COVID-19 VACCINE ASTRAZENECA.. ..On 01-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 01-Dec-2021, the patient experienced BREAST PAIN (Breast pain) (seriousness criterion death). The patient died on 09-Dec-2021. The cause of death was not reported. An autopsy was performed, but no results were provided. . . .The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown.. .For mRNA-1273 (Spikevax) (Unknown), the reporter considered SUDDEN DEATH (Sudden death unexplained) and BREAST PAIN (Breast pain) to have an unknown relationship. . .Autopsy result was pending. .Concomitant product use was not provided by reporter...Treatment information was not provided.
[redacted]		This spontaneous case was reported by a consumer and describes the occurrence of SUDDEN DEATH (Sudden death/died shortly thereafter), LOSS OF CONSCIOUSNESS (patient collapsed) and SALIVARY HYPERSECRETION (salivated) in a 35-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. The occurrence of additional non-serious events is detailed below. . .Previously administered products included for COVID-19 vaccination: ASTRAZENECA COVID-19 VACCINE (first dose) on 13-Apr-2021 and ASTRAZENECA COVID-19 VACCINE (second dose) on 29-Jun-2021..Past adverse reactions to the above products included No adverse event with ASTRAZENECA COVID-19 VACCINE and ASTRAZENECA COVID-19 VACCINE..Concurrent medical conditions included Intellectual disability (congenital intellectual disability with mental age of two to three years.).. ..On 10-Dec-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 10-Dec-2021, the patient experienced INTERCHANGE OF VACCINE PRODUCTS (Previously had received two doses of AstraZeneca COVID-19 vaccine). In December 2021, the patient experienced DECREASED APPETITE (did not eat well). On 30-Dec-2021 at 2:50 AM, the patient experienced LOSS OF CONSCIOUSNESS (patient collapsed) (seriousness criteria death and medically significant) and SALIVARY HYPERSECRETION (salivated) (seriousness criterion death). On 10-Dec-2021, INTERCHANGE OF VACCINE PRODUCTS (Previously had received two doses of AstraZeneca COVID-19 vaccine) had resolved. The patient died on 30-Dec-2021. An autopsy was performed. The autopsy did not show any specific finding, therefore an additional autopsy was requested. At the time of death, DECREASED APPETITE (did not eat well) outcome was unknown. . .The patient had congenital intellectual disability, where the mental age was

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		two to three years. It was reported that he was healthy without any other underlying diseases or medical histories...After the booster dose, the patient did not eat well. At 2:50 AM of 30-DEC-2021, on the way to the toilet, the patient collapsed and salivated and died shortly thereafter. The autopsy performed initially did not show any specific finding. An additional autopsy was requested for further investigation...Company comment: This is a ace of Interchange of vaccine products for this 35-year-old male patient with no relevant medical history. Reportedly, the patient had received two doses of AstraZeneca COVID-19 vaccine and after these doses, the patient had received the mRNA-1273 vaccine (company product) as third dose (booster). Therefore, Interchange of vaccine products is considered in this specific case. The patient developed non serious unexpected event of Decreased appetite, as well as serious unexpected events of Sudden death, Salivary hypersecretion and Loss of consciousness after receiving the mRNA-1273 vaccine, as third dose (booster). The event of Decreased appetite occurred on an unknown date, shortly after vaccination, however, the exact start date was not specified. Twenty days after the vaccination, on the way to the toilet, the patient collapsed and salivated and died shortly thereafter. The autopsy was performed and since it did not show any specific finding, an additional autopsy was requested for further investigation. At the time of this report, it remained unknown if this additional requested autopsy was actually performed. Therefore, the exact cause of death remained unknown at this moment. Limited information precludes a meaningful medical assessment. The rechallenge is not applicable since the patient died. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.
[redacted]		This case was initially received via European Medicines Agency (Reference number: [redacted] on 11-Jan-2022. The most recent information was received on 22-Jan-2022 and was forwarded to Moderna on 22-Jan-2022. .This regulatory authority case was reported by a physician and describes the occurrence of SUDDEN CARDIAC DEATH (death, acute death, possible heart death) in a 73-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 044G21ABS) for COVID-19 immunization. The occurrence of additional non-serious events is detailed below. . .Previously administered products included for Product used for unknown indication: BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0,3ML on 26-Apr-2021, BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3ML on 31-May-2021..Past adverse reactions to the above products included No adverse event with BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0,3ML, BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3ML..Concomitant products included ACETYLSALICYLZUUR for an unknown indication.. ..On 21-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 23-Dec-2021, the patient experienced MYALGIA (Muscle pain). On 25-Dec-2021, the patient experienced MALAISE (Don't feel good). The patient died on 26-Dec-2021. The reported cause of death was acute death, possibly cardiac death. It is unknown if an autopsy was performed. At the time of death, MALAISE (Don't feel good) outcome was unknown and MYALGIA (Muscle pain) had not resolved. . . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .No treatment was reported by the reporter...Company comment: This is an RA case concerning a 73-year-old, male patient with no relevant medical history reported, only use of AAS 80mg as concomitant medication, who experienced the event of sudden cardiac death. Patient received the third dose of mRNA1273 on 21DEC2021 (two previous doses were Covid-19 vaccine Pfizer), two days later started with myalgia, on the 25th reported malaise and passed away on the following day. No further details were provided by the RA, and despite no medical history being reported, it calls attention the fact the patient took AAS 80mg which can suggest a potential cardiovascular comorbidity. The benefit-risk relationship of mRNA-1273 in not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 20-Jan-2022: Due to incorrect follow-up receipt date, this case is amended to reflect the actual follow-up receipt date/Date FU Rcvd by Safety. This case was submitted on-time based on the actual follow-up receipt date. The actual follow-up receipt date/ Date FU Rcvd by Safety for this case is 20-Jan-2022..On 22-Jan-2022: Significant follow up Received ,Batch/lot number Added.
[redacted]		This case was initially received via United Kingdom MHRA (Reference number: [redacted] on 11-Jan-2022. The most recent information was received on 11-Jan-2022 and was forwarded to Moderna on an unknown date...This regulatory authority case was reported by a consumer and describes the occurrence of SUDDEN DEATH (Sudden death) in a patient of an unknown age and gender who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3005287) for an unknown indication. The occurrence of additional non-serious events is detailed below. ..Concomitant products included COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) from 21-Mar-2021 to 04-Jun-2021 for COVID-19...On 05-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced FATIGUE (Fatigue/unusual

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		tiredness). The patient died on 12-Dec-2021. It is unknown if an autopsy was performed. At the time of death, FATIGUE (Fatigue/unusual tiredness) outcome was unknown.. .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On an unknown date, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test...The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown...Patient has not had symptoms associated with COVID-19..Lab tests included was CT scan and autopsy - results not reported.Patient has not tested positive for COVID-19 since having the vaccine. Patient was not enrolled in clinical trial. The report was related to possible inflammation of the heart (myocarditis or pericarditis). The symptoms doesn't lead to a hospital stay. The diagnosis was made by a Radiologist...Treatment medication was not provided by the reporter..Company comment:.This is a regulatory authority case concerning a patient of unknown age and gender, with no relevant medical history reported, who experienced the serious (fatal) unexpected event of sudden death after third dose of mRNA-1273. Cause of death was not reported, the fatal event occurred 8 days after receiving the 3rd dose of mRNA1273. Autopsy was performed with results pending. Primary vaccination completed with AZ product. The benefit-risk relationship of mRNA-1273 in not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 11-Jan-2022: Upon query received from business partner, significant correction was performed on 20-JAN-2022. The cause of death information was removed.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 13-Jan-2022 and was forwarded to Moderna on 13-Jan-2022. .This regulatory authority case was reported by a physician and describes the occurrence of SUDDEN DEATH (sudden death) in an 80-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3005242) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. . .The patient's past medical history included Obesity..Concurrent medical conditions included Hypertension arterial..Concomitant products included TOZINAMERAN (COMIRNATY) from 14-Mar-2021 to an unknown date for COVID-19 vaccination.. ..On 05-Dec-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 07-Dec-2021, the patient experienced SUDDEN DEATH (sudden death) (seriousness criterion death) and IMMUNISATION REACTION (reactogenicity). The patient died on an unknown date. It is unknown if an autopsy was performed. At the time of death, IMMUNISATION REACTION (reactogenicity) outcome was unknown. . . .For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.. .Treatment information was not provided..Patient was previously administered with Pfizer Comirnaty-30 vaccine for adults on 14-MAR-2021 as dose 1 in left arm as intramuscular injection with the lot No .: ET3620 and Pfizer Comirnaty-30 vaccine for adults on 11-APR-2021 as dose 2 in left arm as injection intramuscular with lot No: EW2246.. .Most recent FOLLOW-UP information incorporated above includes:.On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 12-Jan-2022.
[redacted]		This case was initially received via European Medicines Agency (Reference number: [redacted] on 13-Jan-2022. The most recent information was received on 28-Jan-2022 and was forwarded to Moderna on 28-Jan-2022. .This regulatory authority case was reported by a physician and describes the occurrence of CEREBRAL HAEMORRHAGE (Recurrent cerebellar hemorrhage, possibly due to AV formation: This bleeding was in the same place as in may 2021.) in an elderly female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. . .The patient's past medical history included COVID-19 (There were so many complaints that needed hospitalization.), Arteriovenous malformation (In mei 2021, she had cerebellar hemorrhage, possibly from an AV malformation, was in the same place.) in May 2021 and Cerebellar bleeding in May 2021..Previously administered products included for Product used for unknown indication: BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST in May 2021, BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST..Past adverse reactions to the above products included Cerebellar haemorrhage with BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST; and No adverse event with BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST..Concomitant products included COLECALCIFEROL, UMECLIDINIUM and AZITHROMYCIN (AZITROMYCINE) for an unknown indication, SIMVASTATINE.. ..On 22-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, the patient experienced CEREBRAL HAEMORRHAGE (Recurrent cerebellar hemorrhage, possibly due to AV formation: This bleeding was in the same place as in may 2021.) (seriousness criterion death). The patient died on 27-Dec-2021. The reported cause of death was cerebellar hemorrhage, possibly for av malformation. An

Case ID	WW Identifier	Narrative Complete
		autopsy was not performed. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 27-Dec-2021, Blood test: abnormal (abnormal) reported reported had no added value: Hb, Ht, Ery's, MCV, MCH, thrombos: all normal (thrombos 220) Leucos 12.7 (normal 4-10), neutros 11 (normally 1.5-7.5) EOs < 0.030 (normal 0.1-0.5), basos, lymphos and monos: normal. Glucose 20.3, Hepatic function: normal, renal function: urea 12 (normal 2.5-6.4), kreatinine 121 (normal 49-90), eGFR 37 (normal >90), Sodium normal, potassium 3.0 (normal: 3.5-5.0)..On an unknown date, Computerised tomogram head: abnormal (abnormal) At the site of the known AVM/AV fistula with post-hemorrhage status cerebellar right, a large demarquated hyperdens area with hypodency vasogenic edema around best suited to recurrence intra-cerebellar haemorrhage. There is significant mass action on the brain stem with midline shift and transforaminal and uncal herniation of the cerebellar tissue. There is also a bloody breakthrough to the 4th, 3rd and lateral ventricles and the subarachnoidal cistern, phalx and tentorium on both sides. No other relevant findings. No evidence of bleeding, infarction, space-taking processes elsewhere. Intact neurocranium. Conclusion: large cerebellar hemorrhage right with mass action on the brain stem in known AVM/AV fistula cerebellar right with status after bleeding...On an unknown date, SARS-CoV-2 test positive: positive (Positive) Positive.. . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .No treatment information was provided...Company comment: This is a regulatory case concerning an elderly female patient, exact age not provided, with a history of COVID-19, Arteriovenous malformation, Cerebellar hemorrhage possibly due to (1) Arteriovenous malformation and (2) as adverse reaction to the COVID-19 vaccine BioNTech, who experienced the serious Fatal unexpected, AESI of Cerebral haemorrhage. The event occurred on an unknown date after the third dose of mRNA-1273 vaccine. The patient died 5 days after the mRNA-1273 vaccine, the reported cause of death was cerebellar hemorrhage, possibly due to Arteriovenous malformation. A post-mortem CT Scan under contrast showed a large cerebellar hemorrhage right with mass action on the brain stem in known AVM/AV fistula cerebellar right with post-hemorrhage status. An autopsy was not performed. The medical history, of COVID-19, Cerebellar haemorrhage possibly due to (1) Arteriovenous malformation and (2) as an adverse event of BIONTECH vaccine remain as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 27-Jan-2022: Due to incorrect follow-up receipt date, this case is amended to reflect the actual follow-up receipt date/Date FU Rcvd by Safety. This case was submitted on-time based on the actual follow-up receipt date. The actual follow-up receipt date/ Date FU Rcvd by Safety for this case is 27-Jan-2022..On 28-Jan-2022: Patient lab data results, blood test date, dose for conmeds were updated.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted]) on 15-Jan-2022 and was forwarded to Moderna on 15-Jan-2022. .This regulatory authority case was reported by a physician and describes the occurrence of DEATH (fatalities) in an 85-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005242) for COVID-19 vaccination. . .The patient's past medical history included Cardiac arrhythmia, Hypoacusis, Silicosis, Hepatic mass and Hernia inguinal..Concurrent medical conditions included Decompensation cardiac, Diabetes, Hypertension arterial and Ventricular dysfunction..Concomitant products included TOZINAMERAN (COMIRNATY) for COVID-19 vaccination.. ..On 15-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. Death occurred on 15-Dec-2021 The patient died on 15-Dec-2021. It is unknown if an autopsy was performed. . . .The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown.. .For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.. .Treatment details were not provided..Company Comment:.This is a regulatory case concerning an 85-year-old, male patient with medical history including Ventricular dysfunction, Cardiac arrhythmia, Decompensation cardiac, Diabetes, Hypertension arterial, Silicosis and Hepatic mass, with an Interchange of vaccine products (TOZINAMERAN (COMIRNATY) for COVID-19 vaccination), who experienced the unexpected serious event of death. The event occurred approximately on the same day after a dose of mRNA-1273 vaccine. It is unknown if an autopsy was performed. No cause of death was reported. The medical history and patient's age remain as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 14-Jan-2022.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted]) on 14-Jan-2022 and was forwarded to Moderna on 14-Jan-2022. .This regulatory authority case was reported by a physician and describes the occurrence of DEATH (Death unexplained) in an 86-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 057G21A) for COVID-19 vaccination. . .The patient's past medical history included Osteoporosis

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		with fracture, Pseudopolyarthritis and Peripheral arterial occlusive disease..Previously administered products included for COVID-19 vaccination: Pfizer vaccine (Dose 1: Adult Comirnaty-30 Pfizer Vaccine, 20/04/2021, Left Arm, Intramuscular Injection, Lot #: EW4815) on 20-Apr-2021, Pfizer vaccine (Dose 2: Adult Pfizer Comirnaty-30 Vaccine, 18/05/2021, Left Arm, Intramuscular Injection and Lot #: FA4598) on 18-May-2021..Past adverse reactions to the above products included No adverse event with Pfizer vaccine and Pfizer vaccine.. ..On 09-Dec-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. Death occurred on 21-Dec-2021 The patient died on 21-Dec-2021. The cause of death was not reported. An autopsy was not performed. . . .For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.. .No concomitant medications information was reported..No treatment medications were provided.Company Comment:.This is a regulatory case concerning an 86-year-old, male patient with a history of Peripheral arterial occlusive disease, with Interchange of vaccine products (2 prior doses of TOZINAMERAN), who experienced the unexpected serious event of death (unknown cause of death). The event occurred approximately 12 days after the first dose of mRNA-1273 vaccine (third dose in the series). An autopsy was not performed. The medical history and patient's age remain as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The case was assessed as serious as per Regulatory Authority's report due to death.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 21-Jan-2022 and was forwarded to Moderna on 21-Jan-2022. .This regulatory authority case was reported by a physician and describes the occurrence of DEATH (Found dead in apartment on 3.Jan.2022, kneeling in front of the toilet. Significant decay phenomena.) in a 53-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 007G21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. . .Previously administered products included for Product used for unknown indication: Comirnaty BNT162b2 on 12-May-2021 and Comirnaty BNT162b2 on 03-Jun-2021..Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Comirnaty BNT162b2..Concurrent medical conditions included Hypertension and Smoker.. ..On 21-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. In December 2021, the patient experienced NAUSEA (Nausea), VOMITING (Vomiting) and DEATH (Found dead in apartment on 3.Jan.2022, kneeling in front of the toilet. Significant decay phenomena.) (seriousness criterion death). The patient died in December 2021. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, NAUSEA (Nausea) and VOMITING (Vomiting) outcome was unknown. . . .The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown.. .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .Patient medical history mentioned as court ordered an autopsy (Az [redacted]...No concomitant medications were provided by the reporter...No treatment information was provided by the reporter...Company comment: This is a regulatory fatal case that concerns a 53-year-old male patient, with a history of Hypertension and Smoker, who experienced the unexpected fatal event of DEATH. He was found death thirteen days after the dose of the mRNA-1273 with significant decay phenomena. The cause of death was reported unknown. The rechallenge was not applicable as there is no information that states vaccination dose number and there is only one dose reported, and no additional dose is going to be administered. The history of Hypertension and Smoker remain as confounders. The benefit-risk relationship of mRNA-1273 is not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 21-Jan-2022: Non significant information received..On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 20-Jan-2022..On 13-Jun-2022: Due to incorrect follow-up receipt date in live follow-up, this case is amended to reflect the actual follow-up receipt date/Date FU Rcvd by Safety in the narrative. This case was submitted on-time based on previous significant follow-up/initial. The actual follow-up receipt date/ Date FU Rcvd by Safety for this case is 20-Jan-22.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted]) on 21-Jan-2022 and was forwarded to Moderna on 21-Jan-2022. .This regulatory authority case was reported by a physician and describes the occurrence of CARDIAC ARREST (Cardiovascular standstill with resuscitation) in a 52-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005291) for COVID-19 vaccination. . .Previously administered products included for Product used for unknown indication: COMIRNATY on 08-Jun-2021 and COMIRNATY on 20-Jul-2021..Past adverse reactions to the above products included No adverse event with COMIRNATY and COMIRNATY.. ..On 13-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 27-Dec-2021, the patient experienced CARDIAC ARREST (Cardiovascular standstill with resuscitation) (seriousness criteria death and hospitalization). The

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		patient died on 27-Dec-2021. The reported cause of death was Arrest cardiac. An autopsy was not performed. . . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .No concomitant medications were reported .No treatment information was provided..Company Comment:.This case concerns a 52-year-old male patient, with relevant medical history of previous vaccination with COMIRNATY, who experienced the unexpected serious event of Cardiac arrest. The event occurred approximately 14 days after receiving a dose of mRNA-1273 Vaccine which resulted in hospitalization and a fatal outcome. The reported cause of death was Arrest cardiac. An autopsy was not performed. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 20-Jan-2022.
[redacted]		This spontaneous case was reported by a consumer and describes the occurrence of MYOCARDIAL INFARCTION (Heart attack (heart attack (10019250), Myocardial infarction (10028596))) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for Prophylactic vaccination. . .Co-suspect product included non-company product COVID-19 VACCINE NRVV AD26 (JNJ 78436735) (JANSSEN COVID-19 VACCINE) for Prophylactic vaccination.. .No Medical History information was reported.. .On 17-Dec-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form..On an unknown date, the patient received first dose of COVID-19 VACCINE NRVV AD26 (JNJ 78436735) (JANSSEN COVID-19 VACCINE) (unknown route) 1 dosage form. On 18-Dec-2021, the patient experienced MYOCARDIAL INFARCTION (Heart attack (heart attack (10019250), Myocardial infarction (10028596))) (seriousness criteria death and medically significant). The patient died on 18-Dec-2021. The reported cause of death was heart attack (heart attack(10019250), myocardial infarction (10028596)). It is unknown if an autopsy was performed. . . .For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter considered MYOCARDIAL INFARCTION (Heart attack (heart attack (10019250), Myocardial infarction (10028596))) to have an unknown relationship. . .No concomitant medication were provided...Patient received JANSSEN COVID-19 vaccine as their 1st dose vaccine...No treatment information were reported...Company Comment: This spontaneous case concerns a male patient, of unknown age, with history of co-suspect administration of the Janssen COVID-19 vaccine, who experienced the unexpected, serious AESI of myocardial infarction. The event, which resulted in a fatal outcome, occurred 1 day after administration of the second dose of the Moderna mRNA-1273 vaccine. On 18Dec2021, the patient experienced a heart attack and died. No further details were provided. It is unknown if an autopsy was performed. The history of co-suspect administration of the Janssen COVID-19 vaccine remains a confounder. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 21-Jan-2022 and was forwarded to Moderna on 21-Jan-2022. .This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (cause of death unknown) in a 90-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. . .Previously administered products included for Prophylactic vaccination: Comirnaty BNT162b2 on 25-Nov-2021..Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2..Concurrent medical conditions included Dementia.. ..On 30-Nov-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 4 dosage form. Death occurred on 01-Dec-2021 The patient died on 01-Dec-2021. The cause of death was not reported. It is unknown if an autopsy was performed. . . . . .Concomitant drugs were not reported..Treatment medications were not provided...It was reported that on 25-Nov-2021 patient had third booster with biontech and on 30-Nov-2021 patient had fourth boosting with Moderna vaccine...Company comment:.This Regulatory authority case concerns a 90-year-old, female patient, with medical history of dementia, who experienced the unexpected, serious (fatal) event of death. The event occurred 1 day after receiving a dose of mRNA-1273 vaccine, considered as the fourth dose of her COVID-19 vaccination schedule. It was reported that the patient received a third boosting dose in a hospital 5 days prior vaccination with mRNA-1273 vaccine at the same hospital. Due to underlying condition, it was reported that she could not say she had already been vaccinated with the booster dose. The patient died 1 day after vaccination and the cause of death was reported as unknown. Autopsy report is not available. The medical history of dementia remains as a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 20-Jan-2022.

Case ID	WW Identifier	Narrative Complete
[redacted]	[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 21-Jan-2022 and was forwarded to Moderna on 21-Jan-2022. ..This regulatory authority case was reported by a physician and describes the occurrence of ARRHYTHMIA (Arrhythmia cardiac (NOS)) in an 85-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 000128A) for COVID-19 vaccination. . .Previously administered products included for COVID-19 vaccination: Comirnaty BNT162b2 on 21-Jul-2021..Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2.. .On 05-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, the patient experienced ARRHYTHMIA (Arrhythmia cardiac (NOS)) (seriousness criterion death). The cause of death was not reported. It is unknown if an autopsy was performed. . .The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown.. .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .Concomitant product use was not provided. Treatment information was not provided..It was reported that Date of death was not communicated. Reported cause of death was Unknown cause of Death. ..Company comment: This regulatory authority case concerns a 85-year-old female patient with no medical history reported, who experienced the unexpected fatal event of Arrythmia (AESI) in association with mRNA- 1273 vaccine, dose number unknown. The patient had received prior dose of Comirnaty vaccine. Temporal association of the event with mRNA- 1273 vaccine is not assessable since the onset date of the event was not disclosed. The fatal outcome occurred on an unknown date. Very limited information is available regarding clinical course, medical assessment and circumstances leading to death. Cause of death was reported as Unknown. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 20-Jan-2022.
[redacted]	[redacted]	This regulatory authority case was reported by a physician and describes the occurrence of NAUSEA (nausea), HEADACHE (headache), PULMONARY EMBOLISM (Pulmonary embolism), SYNCOPE (Syncope vasovagal) and DEEP VEIN THROMBOSIS (DVT) in a 51-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. . .Patient has not had symptoms associated with COVID-19. Patient is not pregnant,.Patient is not currently breastfeeding. .The patient's past medical history included Lumbar puncture, Non-smoker and Migraine (Migraine on a Triptan)..Concomitant products included COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) from 25-Mar-2021 to 30-May-2021 and COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) from 25-Mar-2021 to an unknown date for COVID-19 vaccination, AMITRIPTYLINE and NARATRIPTAN for Migraine.. ..On 03-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced NAUSEA (nausea) (seriousness criterion medically significant), HEADACHE (headache) (seriousness criterion medically significant), PULMONARY EMBOLISM (Pulmonary embolism) (seriousness criteria death and medically significant), SYNCOPE (Syncope vasovagal) (seriousness criterion medically significant) and DEEP VEIN THROMBOSIS (DVT) (seriousness criterion medically significant). The patient died on 15-Jan-2022. The reported cause of death was dvt and Pulmonary embolism. An autopsy was performed, but no results were provided. At the time of death, NAUSEA (nausea), HEADACHE (headache) and DEEP VEIN THROMBOSIS (DVT) had not resolved and SYNCOPE (Syncope vasovagal) outcome was unknown. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 12-Jan-2022, Platelet count: 223 (Inconclusive) 223..On an unknown date, Blood fibrinogen: 3.8 (Inconclusive) 3.8..On an unknown date, Prothrombin time: 14.3 (Inconclusive) 14.3..On an unknown date, SARS-CoV-2 test: no - negative covid-19 test (Negative) No - Negative COVID-19 test.. . .For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.. .Patient was White British..No treatment drugs were reported..Reported that patient was admitted with headache and nausea, had not felt well since booster. Had collapse at home, which thought to be vasovagal. ..Reported that patient was admitted with collapse which thought to be a vasovagal, patient discharged 2 days later. Patient died at home, Post mortem showed Pulmonary embolism secondary to DVT (deep vein thrombosis)...She had prophylactic enoxaparin (40mg) whilst an inpatient, she presented with headache and nausea and therefore never had a CT pulmonary angiogram (CTPA) to diagnose it. ..Relevant investigations or tests conducted include computerised tomography (CT) Head..The platelet count was not <150 Ã— 109/L and it was unknown if D-dimer >4000, it was unknown if anti-PF4 antibodies identified...Last platelet count before vaccine (usual normal range 150-450): 223 on 12/01/22...Reported lab data include PT: 14.3, Fibrinogen: 3.80..She had no scans, Pulmonary embolism (PE) was discovered on post mortem along with a DVT...Reported that patient

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		does not confirmed or suspected autoimmune or inflammatory disease, including vasculitis. Patient not had any previous reactions to medications, especially heparin or anticoagulants. Patient does not have history of, or current, malignancy. Patient does not have a history of, or concurrent, intracranial malignancy. Patient does not have concurrent or recent intracranial infections. Patient has not had recent surgical or medical interventions to the central nervous system (including lumbar puncture). Patient has not had a recent trauma/head injury. Haemorrhage was not identified...Reported that not aware if patient had been diagnosed with COVID 19...Report relates to possible blood clots or low platelet counts and does not relate to myocarditis or pericarditis.This is a regulatory case concerning a 51-year-old female patient with no relevant medical history. .Most recent FOLLOW-UP information incorporated above includes:.On 03-Feb-2022: Follow-up received suspect and conmed information updated, newconmeds added, new info to I-narrative added. Seriousness criteria medically significant ticked as per SD..On 09-Feb-2022: Non significant follow up received contain no new information
[redacted]	[redacted]	This case was initially received via European Medicines Agency (Reference number: [redacted] on 22-Jan-2022. The most recent information was received on 11-Mar-2022 and was forwarded to Moderna on 11-Mar-2022. .This regulatory authority case was reported by a physician and describes the occurrence of RESUSCITATION (19/12/2021 19 hr: collapsed, CPR), RECTAL HAEMORRHAGE (19/12/2021, 6.38 am: a lot of rectal blood loss), CIRCULATORY COLLAPSE (19/12/2021 19 hr: collabed, resuscitation) and ABDOMINAL PAIN (19/12/2021 06.38 hr: Abdominal pain; seen on SEH, suspected GE/food poisoning of spoiled fish.) in a 77-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. . .The patient's past medical history included Pancreatitis in 2001, Morbid obesity (BMI 36.8, lost 5 kg compared to the year before) in 2021, Fracture of head of radius, open (Distal radius fracture left) in 1989, Dyspnoea (Been ill with dyspnea and fever in early and mid-2020. At the time, testing was not available usual. Restored without AB usage. May have been Covid, but can no longer be traced) in 2020, Type 1 diabetes mellitus in 1991, Trigger finger in 2009, Cholangitis in 2006, Tibia fracture (lower leg fracture right) in 1986, Trigger finger release (there was no family history) in 2009, Agoraphobia (supervised by POH GGZ), Gallstones (ERCP with papillotomy, cholecystectomy) in 1996 and Neurolysis (Release N medianus right, April 2014: neurolysis without operating microscope or loupe magnification) in 2014..Previously administered products included for Drug use for unknown indication: COVID-19 vaccine Pfizer COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST on 14-Apr-2021, COVID-19 vaccine Pfizer COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST on 20-May-2021..Past adverse reactions to the above products included No adverse event with COVID-19 vaccine Pfizer COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST, COVID-19 vaccine Pfizer COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST..Concurrent medical conditions included Hypertension..Concomitant products included AZITHROMYCIN (AZITROMYCINE) from 17-Dec-2021 to an unknown date for Sinusitis, INSULIN and HYDROCHLOORTHIAZIDE for an unknown indication.. ..On 13-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 17-Dec-2021, the patient experienced BLOOD GLUCOSE FLUCTUATION (17/12 GP consulted for sinus complaints, glucose fluctuations and headache), HEADACHE (17/12 GP consulted for sinus symptoms, glucose fluctuations and headaches) and SINUSITIS (17/12 GP consulted for sinus symptoms, glucose fluctuations and headaches). On 18-Dec-2021, the patient experienced VOMITING (18/12/21, 21 hr: abdominal pain, diarrhea and vomiting), DIARRHOEA (18/12/21, 9:00 pm: abdominal pain, diarrhea and vomiting), GASTROINTESTINAL PAIN (18/12/21, 9:00 pm: abdominal pain, diarrhea and vomiting) and ABDOMINAL PAIN (19/12/2021 06.38 hr: Abdominal pain; seen on SEH, suspected GE/food poisoning of spoiled fish.) (seriousness criterion death). On 19-Dec-2021, the patient experienced RESUSCITATION (19/12/2021 19 hr: collapsed, CPR) (seriousness criterion death), RECTAL HAEMORRHAGE (19/12/2021, 6.38 am: a lot of rectal blood loss) (seriousness criterion death), HAEMATOCHEZIA (19/12/2021 06.38 hr: stomach ache; seen at ED, suspected GE/food poisoning from spoiled fish. Some blood in faeces) and CIRCULATORY COLLAPSE (19/12/2021 19 hr: collabed, resuscitation) (seriousness criterion death). The patient died on 19-Dec-2021. The reported cause of death was a lot of rectal bleeding. An autopsy was not performed. At the time of death, HAEMATOCHEZIA (19/12/2021 06.38 hr: stomach ache; seen at ED, suspected GE/food poisoning from spoiled fish. Some blood in faeces), BLOOD GLUCOSE FLUCTUATION (17/12 GP consulted for sinus complaints, glucose fluctuations and headache), VOMITING (18/12/21, 21 hr: abdominal pain, diarrhea and vomiting), DIARRHOEA (18/12/21, 9:00 pm: abdominal pain, diarrhea and vomiting), HEADACHE (17/12 GP consulted for sinus symptoms, glucose fluctuations and headaches), SINUSITIS (17/12 GP consulted for sinus symptoms, glucose fluctuations and headaches) and GASTROINTESTINAL PAIN (18/12/21, 9:00 pm: abdominal pain,

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		diarrhea and vomiting) outcome was unknown. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 14-Oct-2020, Physical examination: abnormal (abnormal) RR 134/55, MAP: 81.3, height 1.59 cm, weight 98 kg and normal (normal) BP 134/55, MAP: 81.3, height 1.59 cm, weight 98 kg..On 20-Apr-2021, Ophthalmological examination: normal (normal) left eye: no abnormalities, right eye: no abnormalities and normal (normal) left eye: no abnormalities, right eye: no abnormalities..On 13-Oct-2021, Glycosylated haemoglobin: 52 (normal) 52= high for non-diabetics, but well-set diabetic should have < 53, so ok...On 13-Oct-2021, Laboratory test: abnormal (abnormal) Hb 7.4 (net te laag), HT 0.36 (LLN), MCV 88 fl, trombo's 252 (normal), leuko's 4.5 (normal), Natrium 141 (normal) , Kalium 4.3 (normal), and normal (normal) Hb 7.4 (net te laag), HT 0.36 (LLN), MCV 88 fl, trombo's 252 (normal), leuko's 4.5 (normal), Natrium 141 (normal) , Kalium 4.3 (normal)..On 13-Oct-2021, Liver function test: abnormal (abnormal) ALAT 16, Cholesterol 3.5, HDL cholesterol 1.3, non-HDL cholesterol: 2.2 (= low) and low (Low) ALT 16, Cholesterol 3.5, HDL cholesterol 1.3, non- HDL cholesterol: 2.2 (= low)..On 13-Oct-2021, Renal impairment: abnormal (abnormal) Kreatinine 105 (high, ULN: 100), EGFR (CKD-EPI): 44 = moderate renal impairment..On 20-Oct-2021, Physical examination: abnormal (abnormal) RR 138/70, MAP: 92.7, height 1.59 cm, weight 93 kg, BMI 36.8 BSA 1.94 and normal (normal) BP 138/70, MAP: 92.7, height 1.59 cm, weight 93 kg, BMI 36.8 BSA 1.94..On 19-Dec-2021, Blood glucose: 16.7 (High) On SEH: 16.7..On 19-Dec-2021, Liver function test: abnormal (abnormal) on SEH: alk phosph 103 other liver enzymes not abnormal and 103 (normal) on emergency room: alk fosf 103 other liver enzymes not abnormal..On 19-Dec-2021, Physical examination: abnormal (abnormal) 0.38 hr on 19/12/2021: T 35.9, vivid intestinal peristalsis, pressure pain epigastrio upper left., abnormal (abnormal) 06.38 hr: RR 130/70, pols 77, sat 97%., normal (normal) 06.38 hr: RR 130/70, pols 77, sat 97%. and abnormal (abnormal) 00:38 am on 19/12/2021: T 35.9, vivid intestinal peristalsis,pressure pain epigastrio upper left...On 19-Dec-2021, Renal impairment: abnormal (abnormal) SEH : eGFR 41 (was 44 2 months ago) , creatinine 111 (was 105 2 months ago).. . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .Additional information on azithromycin drug was as follow:Patient had sinus symptoms from +/- 1 dec for which she was using Otrivin. On 17/12 tel. consult informed "TC: persistent sinus symptoms, headaches and rising sugars. Patient had no fever, no rhinitis. Nasal spray does not help, Patient seen weekend and rising sugars yet blind cure: Patient took Azithromycin 500mg 1d1t, 3 dgn...No treatment medications were provided...Company comment: This regulatory authority case concerns a 77-year-old female patient, with medical history of Morbid obesity, hypertension, Type 1 diabetes Mellitus, and interchange of vaccine products (PFIZER COVID-19 vaccine), who experienced the serious (fatal), unexpected events of rectal hemorrhage, abdominal pain, circulatory collapse and resuscitation. The patient consulted a physician 4 days after receiving the dose of mRNA-1273 COVID-19 vaccine (3rd dose in the series) due to sinus complaints, glucose fluctuation and headaches. Five days after the vaccine, patient diarrhea, and gastrointestinal pain. Six days after the vaccine, patient had abdominal pain and was seen on SEH, she was suspected to have gastroenteritis/food poisoning due to spoiled fish. At SEH, blood glucose was 16.7 (no measurement unit) liver function test was abnormal, eGFR was decreased 41, on physical examination she had te
[redacted]		This case was initially received via European Medicines Agency (Reference number: [redacted] on 22-Jan-2022. The most recent information was received on 11-Feb-2022 and was forwarded to Moderna on 11-Feb-2022. .This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDIAL INFARCTION (myocardial infarction) in an 80-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. . .The patient's past medical history included Myocardial infarction in 2015..Previously administered products included for Product used for unknown indication: BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST on 18-Mar-2021, BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST on 26-Apr-2021..Past adverse reactions to the above products included No adverse reaction with BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST, BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST..Concurrent medical conditions included Atrial fibrillation, Diabetes mellitus, Obesity (BMI >32), Benign paroxysmal positional vertigo (Complaining of dizziness matching orthostasis and BPPD for a long time), Hypertension and Orthostatic dizziness (Complaining of dizziness matching orthostasis and BPPD for a long time)..Concomitant products included METFORMIN (METFORMINE [METFORMIN]), FUROSEMIDE (FRUSEMIDE [FUROSEMIDE]), ACENOCOUMAROL, INSULIN ISOPHANE PORCINE (INSULINE NPH), OMEPRAZOLE (OMEPRAZOL A), ATORVASTATIN (ATORVASTATINE [ATORVASTATIN]), GLIMEPIRIDE, VALSARTAN, PAROXETINE (PAROXETIN [PAROXETINE]), METOPROLOL, MORPHINE

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		(METOPROLOL;MORPHINE) and BARNIDIPINE for an unknown indication.. ..On 02-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 05-Jan-2022, the patient experienced MYOCARDIAL INFARCTION (myocardial infarction) (seriousness criterion death). The patient died on 05-Jan-2022. The reported cause of death was myocardinfarct. An autopsy was not performed. . . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .No treatment information was provided...Company comment:.This is a regulatory authority case concerning a 80-year-old, female patient with relevant medical history of myocardial infarction and concurrent medical conditions of atrial fibrillation, diabetes mellitus, hypertension and obesity (BMI >32) and vaccine history of receiving 2 doses of another brand of Covid-19 vaccine (Covid-19 vaccine Comirnaty) as previous doses, who experienced the unexpected, serious, AESI event of myocardial infarction. The event myocardial infarction occurred approximately 3 days after the unknown dose number of mRNA-1273 vaccine administration. The outcome of the event myocardial infarction was fatal. The reported cause of death was myocardial infarction. Autopsy was not performed. The medical history of myocardial infarction and concurrent medical conditions of atrial fibrillation, diabetes mellitus, hypertension and obesity remain confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 11-Feb-2022: Patient medical history added, autopsy details and concomitant drug details updated..On 11-Feb-2022: Translation document received on 17 FEB 2022 with event verbatim updated..On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 20-Jan-2022.
[redacted]		This case was initially received via European Medicines Agency (Reference number [redacted] on 25-Jan-2022. The most recent information was received on 24-May-2022 and was forwarded to Moderna on 24-May-2022. .This regulatory authority case was reported by a physician and describes the occurrence of SUDDEN DEATH (Sudden death) in a 55-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 094F21A) for COVID-19 vaccination. . .The patient's past medical history included Humerus fracture (Assaulted by drunk neighbor.) in 2019, Patella fracture, Fractured mandible in September 2020, Rupture of spleen (In connection with a car accident.) in 2019, Fractured finger (Assaulted by drunk neighbor.) in 2019 and Radius fracture in September 2020..Previously administered products included for Vaccination: COMIRNATY and COMIRNATY..Past adverse reactions to the above products included No adverse event with COMIRNATY and COMIRNATY..Concurrent medical conditions included Ulcus ventriculi, Transaminases increased, Osteopenia, Smoker, Alcohol problem (Phosphatidylethanol (PEth): very high values.), Prolapsed disc NOS in 2002 and Cholecystitis.. ..On 27-Dec-2021 at 4:59 PM, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. The patient died on 29-Dec-2021. The cause of death was not reported. It is unknown if an autopsy was performed. . . .For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered SUDDEN DEATH (Sudden death) to be unlikely related. . .Concomitant product usage were not provided. Treatment details were not provided...Patient was found dead on the sofa in his own home on December 29, it was unclear if it was due to the vaccine...Company comment:.This Regulatory case reported by a physician, concerns a 55-year-old female patient with concurrent medical conditions of Gastric ulcer (Ulcus ventriculi), Transaminases increased, Osteopenia, currently smoking, having Alcohol problem and Cholecystitis, who experienced the serious (fatal) unexpected event of Sudden death. The event occurred two days after the third dose of mRNA-1273, in the covid 19 vaccination series. Previously administered products for Vaccination included 2 doses of Comirnaty, with no adverse events reported. Interchange of vaccine products is noted. The cause of death was not provided. It is also unknown if an autopsy was performed. Very limited information provided precluding a comprehensive assessment. Causality is confounded with patient's current history of smoking and alcohol use. The benefit-risk relationship of mRNA-1273 is not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 24-May-2022: Significant Follow up - Causality updated from possible to unlikely, Reporter's comment updated..On 24-May-2022: Translated document attached.
[redacted]		This spontaneous case was reported by a consumer and describes the occurrence of MYOCARDIAL INFARCTION (Heart Attack) in a 49-year-old patient of an unknown gender who received mRNA-1273 (Moderna COVID-19 Vaccine) for Prophylactic vaccination. . .Co-suspect product included non-company product COVID-19 VACCINE NRVV AD26 (JNJ 78436735) (JANSSEN COVID-19 VACCINE) for Prophylactic vaccination.. .No Medical History information was reported.. .On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form and first dose of COVID-19 VACCINE NRVV AD26 (JNJ 78436735) (JANSSEN COVID-19 VACCINE) (unknown route) 1 total. On an unknown date, the patient

Case ID	WW Identifier	Narrative Complete
		experienced MYOCARDIAL INFARCTION (Heart Attack) (seriousness criteria death and medically significant). The reported cause of death was Heart attack. It is unknown if an autopsy was performed. . . . . .Concomitant drug details not provided..The patient received mRNA-1273 (Moderna COVID-19 Vaccine) after receiving COVID-19 VACCINE NRVV AD26 (JNJ 78436735) (JANSSEN COVID-19 VACCINE). On an unspecified date, following vaccination with mRNA-1273, the patient had a heart attack. On the next day (after vaccination) the patient died due to heart attack. No treatment information was provided...Company Comment - .This case concerns a 49 year old patient of unknown gender with no relevant medical history, who experienced the serious unexpected event of myocardial infarction. The event occurred on an unknown date after a dose of mRNA-1273 vaccine. The outcome was fatal , with death occurring 1 day after receiving a dose of mRNA-1273 vaccine. The reported cause of death was heart attack. The rechallenge was not applicable. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.
[redacted]	[redacted]	This spontaneous case was reported by a consumer and describes the occurrence of PULMONARY THROMBOSIS (Patient died due to a massive blood clot on her lungs) in a 66-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. . .No Medical History was provided by reporter. .Previously administered products included for Drug use for unknown indication: Pfizer covid-19 vaccine (1st dose, Batch number: EN6207) on 15-Mar-2021, Pfizer covid-19 vaccine (2nd dose and Batch number: EW0150) on 05-Apr-2021..Past adverse reactions to the above products included No adverse event with Pfizer covid-19 vaccine and Pfizer covid-19 vaccine..Concomitant products included CLOPIDOGREL BISULFATE (PLAVIX) for Anticoagulant therapy.. ..On 17-Nov-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 18-Nov-2021, the patient experienced FEELING OF BODY TEMPERATURE CHANGE (Hot and cold), DISCOMFORT (Patient had an uncomfortable day) and DIZZINESS (Dizziness). On 06-Dec-2021, the patient experienced PULMONARY THROMBOSIS (Patient died due to a massive blood clot on her lungs) (seriousness criteria death and medically significant). On 19-Nov-2021, FEELING OF BODY TEMPERATURE CHANGE (Hot and cold), DISCOMFORT (Patient had an uncomfortable day) and DIZZINESS (Dizziness) had resolved. The patient died on 06-Dec-2021. The reported cause of death was patient died due to a massive blood clot on her lungs. It is unknown if an autopsy was performed. . . . . .No treatment information was provided..Husband mentioned that previous to the administration of the booster to his wife, there where warning signs to not to get the Moderna vaccine, and to get a stronger blood thinner.first. The reporter stated he would consult the case with a lawyer...Company Comment-.This is a fatal case that concerns a 66-year-old female patient with no medical history, who experienced the unexpected serious adverse event of special interest, Pulmonary Thrombosis. The event was medically significant and caused the sudden demise of the patient. The event occurred in 20 days after receiving the third dose of mRNA-1273 Vaccine. The patient died on 06-Dec-2021. The reported cause of death was patient died due to a massive blood clot on her lungs. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.. .Reporter did not allow further contact
[redacted]	[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 27-Jan-2022 and was forwarded to Moderna on 27-Jan-2022. .This regulatory authority case was reported by a physician and describes the occurrence of NAUSEA (Nausea), ASTHENIA (General debility), DEATH (Found dead (cause undetermined)), DIZZINESS (Light headedness), DIARRHOEA (Diarrhoea), DEHYDRATION (Exsiccosis) and MALAISE (Malaise) in a 78-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. . .The patient's past medical history included Adrenal insufficiency, Hashimoto's thyroiditis and Vitamin B12 deficiency..Previously administered products included for COVID-19 vaccination: Comirnaty and VAXZEVRIA..Past adverse reactions to the above products included No adverse event with Comirnaty and VAXZEVRIA.. ..On 04-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 05-Dec-2021, the patient experienced ASTHENIA (General debility) (seriousness criterion death) and MALAISE (Malaise) (seriousness criterion death). On 08-Dec-2021, the patient experienced NAUSEA (Nausea) (seriousness criterion death), DIZZINESS (Light headedness) (seriousness criterion death), DIARRHOEA (Diarrhoea) (seriousness criterion death) and DEHYDRATION (Exsiccosis) (seriousness criterion death). The patient died on 09-Dec-2021. The cause of death was not reported. It is unknown if an autopsy was performed. . . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .Concomitant Medication use information was not provided by reporter...Treatment Medication use information was not provided by reporter...Company comment: This case concerns a 78-year-old female patient, with medical history of adrenal insufficiency, who experienced the serious (fatal), unexpected events of nausea, asthenia, dizziness, diarrhea, dehydration, and malaise. The patient

Case ID	WW Identifier	Narrative Complete
		experienced asthenia and malaise 1 day after the third dose of mRNA 1273 COVID-19 vaccine. Four days after vaccine, patient had nausea, dizziness, diarrhea and dehydration. The patient died 5 days after the vaccine. The cause of death was undetermined. It is unknown if an autopsy was done. The patient received COVID-19 vaccines: COMIRNATY AND VAXZEVRIA on unknown date prior to the mRNA 1273 vaccine. The patient's age and medical history of adrenal insufficiency remain as confounder to the events. The benefit-risk relationship of mRNA 1273 vaccine is not affected by this report.
[redacted]		This case was initially received via European Medicines Agency (Reference number: [redacted] on 28-Jan-2022. The most recent information was received on 29-Jan-2022 and was forwarded to Moderna on 29-Jan-2022. .This regulatory authority case was reported by a consumer and describes the occurrence of SUDDEN DEATH (He died 10 days after the third dose of Moderna after the first two of pfizer, of internal bleeding without any obvious or apparent malaise.) in a 59-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 094F21A) for COVID-19 vaccination. . .Previously administered products included for SARS-CoV-2 vaccination: COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03) on 13-May-2021 and COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03) on 17-Jun-2021..Past adverse reactions to the above products included No adverse event with COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03) and COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03).. ..On 16-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. The patient died on 26-Dec-2021. It is unknown if an autopsy was performed. . . . . .Concomitant product use was not provided by the reporter...Patient had not any kind of illness. Patient did not took any kind of medication, except some ibuprofen for sporadic headaches as treatment...Company comment: This is a regulatory case concerning a 59-year-old, male patient with no relevant medical history, who experienced the unexpected, Fatal event of Sudden death. The event occurred 10 days after the unknown dose of mRNA-1273 vaccine administered on 16-Dec-21 for the indication of COVID-19 vaccination. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The case was assessed as Serious as per Regulatory Authority report.. .Most recent FOLLOW-UP information incorporated above includes:.On 29-Jan-2022: Follow up received included event coding was updated from internal hemorrhage to sudden death..On 14-Feb-2022: Follow-up information received on 14-Feb-2022 and contains non-significant information..On 14-Jun-2022: Follow up received that contains No New Information.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 28-Jan-2022 and was forwarded to Moderna on 28-Jan-2022. .This regulatory authority case was reported by a physician and describes the occurrence of VENTRICULAR FIBRILLATION (Fibrillation ventricular) in a 61-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. . .The patient's past medical history included Ex-tobacco user (16PA)..Concomitant products included TOZINAMERAN (COMIRNATY) for Revaccination with different COVID-19 vaccine.. ..On 05-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On 05-Jan-2022, the patient experienced VENTRICULAR FIBRILLATION (Fibrillation ventricular) (seriousness criterion death). The patient died on 06-Jan-2022. The reported cause of death was cardiac arrest on ventricular fibrillation. An autopsy was not performed. . . .For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.. .No concomitant medication was reported..No treatment information was provided...Company comment: This case concerns a 61-year-old female patient, Ex-tobacco user, who experienced fatal VENTRICULAR FIBRILLATION. The patient developed VENTRICULAR FIBRILLATION on the same day after received a dose of mRNA-1273 and died on the following day. The reported cause of death was cardiac arrest on ventricular fibrillation. An autopsy was not performed. Th patient's history of smoking remains confounding. The reporter did not provide causality assessment. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.
[redacted]		This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 27-Jan-2022. The most recent information was received on 04-Feb-2022 and was forwarded to Moderna on 08-Feb-2022. .This case was reported by a physician via the Drug Information Center. On 04-Feb-2022, follow-up information, reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, [redacted]. On 19-Jun-2021, the patient received the 1st dose of SARS-CoV-2 (coronavirus modified uridine RNA vaccine). On 10-Jul-2021, the patient received the 2nd dose of SARS-CoV-2 (coronavirus modified uridine RNA vaccine). On an unknown date, body temperature before the vaccination: 36.7 degrees Celsius. On 23-Jan-2022, at 17:00, the patient received the 3rd vaccination with this vaccine. On 24-Jan-2022, at 10:45, the patient noticed shortness of breath and visited another hospital. After returning home, the patient was transported to the reporting hospital by ambulance in cardio-respiratory arrest. Although

Case ID	WW Identifier	Narrative Complete
		resuscitation was performed, no return of spontaneous circulation was noted. At 12:03, the patient was confirmed dead. CT scan showed suspected acute aortic dissection. The cause of death was acute aortic dissection. The outcome of shortness of breath, cardio-respiratory arrest, and acute aortic dissection was reported as fatal. Follow-up investigation will be made. Reporter comments continuation: It is unknown whether shortness of breath was due to an adverse reaction after the vaccination with this vaccine or a symptom of acute aortic dissection. In addition, the association between vaccination with the vaccine and acute aortic dissection cannot be ruled out. As another factor, shortness of breath may have been caused by acute aortic dissection. Follow-up received on 04-FEB-2022 Updated: Reporter Information, Patient Information, Lab Data, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
[redacted]		This case was initially received via United Kingdom MHRA (Reference number: [redacted] on 28-Jan-2022. The most recent information was received on 02-Feb-2022 and was forwarded to Moderna on 02-Feb-2022...This regulatory authority case was reported by an other health care professional and describes the occurrence of PYREXIA (high temperature), TACHYCARDIA (Tachycardia), HYPERTENSION (Hypertension) and OXYGEN SATURATION DECREASED (Oxygen saturation decreased) in a 79-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. ..The patient's past medical history included Pulmonary fibrosis, Chest infection, Breathlessness, Oxygen saturation low, Arthritis and COVID-19 in November 2021..Previously administered products included for Product used for unknown indication: Steroid therapy (Taking regular steroid treatment (e.g. orally or rectally))..Past adverse reactions to the above products included No adverse reaction with Steroid therapy..Concurrent medical conditions included Hypertension..Concomitant products included SALBUTAMOL for Breathing difficult, DOXYCYCLINE from 11-Jan-2022 to 17-Jan-2022 for Chest infection, ATORVASTATIN for Cholesterol, MORPHINE for Pain, TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) from 30-Jan-2021 to an unknown date for Vaccination...On 13-Jan-2022, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 13-Jan-2022, the patient experienced TACHYCARDIA (Tachycardia) (seriousness criteria death and hospitalization). On an unknown date, the patient experienced PYREXIA (high temperature) (seriousness criterion hospitalization), HYPERTENSION (Hypertension) (seriousness criterion hospitalization) and OXYGEN SATURATION DECREASED (Oxygen saturation decreased) (seriousness criterion hospitalization). The patient died on 26-Jan-2022. An autopsy was not performed. At the time of death, PYREXIA (high temperature), HYPERTENSION (Hypertension) and OXYGEN SATURATION DECREASED (Oxygen saturation decreased) had not resolved.. .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On an unknown date, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test...For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.. .The concomitant medication included DEXAMETASONE used for an unknown indication. Patient has not tested positive for COVID-19 since having the vaccine. He was not enrolled in clinical trial...Previous COVID infection in Nov 2021 which had reduced lung functioning, hypertension, arthritis. Admitted to hospital 10/1/22 for low oxygen saturation, SOB, chest infection. Palliative care review for breathlessness on admission. He was tachycardic, low BP increased HR and low oxygen levels. High temperature within an hour of covid vaccination. His poor condition due to comorbidities prior to vaccine, but onset of symptoms post vaccination. He had severe pulmonary fibrosis and on long term oxygen. Unsure if he has had symptoms associated with COVID-19. He died on 26-Jan-2022...Company Comment: This is a RA case concerning a 79-year-old male patient, with medical history of COVID-19 infection which had reduced lung functioning, pulmonary fibrosis, chest infection, breathlessness, hypertension, oxygen saturation low, and arthritis, who experienced the unexpected and serious events of Pyrexia, Hypertension, and Tachycardia. Patient received Pfizer vaccine against COVID-19, and 1 year later received a third dose with mRNA-1273 (Moderna covid-19 vaccine). The events occurred the same day after the third dose with mRNA-1273 vaccine. Patient died 13 days after vaccination. This patient poor medical conditions prior to vaccination remains a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 02-Feb-2022: Follow up received wherein, events and lab data was added, outcome of events high temperature and Tachycardia were updated..On 02-Feb-2022: Upon query received from business partner, Non-Significant correction was performed on 15-FEB-2022. Updated Concomitant medication Dexametasone.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 31-Jan-2022 and was forwarded to Moderna on 31-Jan-2022. .This regulatory authority case was reported by a physician and describes the occurrence of PYREXIA (Pyrexia), SUDDEN DEATH

Case ID	WW Identifier	Narrative Complete
		(Sudden death unexplained), DROP ATTACKS (Drop attacks) and ATONIC SEIZURES (Drop seizures) in an 83-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3001651) for COVID-19 vaccination. . .Previously administered products included for COVID-19 vaccination: COVID-19 mRNA Vaccine COVID-19 mRNA Vaccine (nucleoside modified)COVID-19 Vaccine Moderna dispersion for injectionSpykeVax (Spikevax COVID-19 mRNA Vaccine (nucleoside modified)COVID-19 Vaccine Moderna dispersion for injectionSpykeVax) on 23-Mar-2021 and COVID-19 VACCINE (Spikevax COVID-19 mRNA Vaccine (nucleoside modified)COVID-19 Vaccine Moderna dispersion for injectionSpykeVax) on 21-Apr-2021..Past adverse reactions to the above products included No adverse event with COVID-19 VACCINE and COVID-19 mRNA Vaccine COVID-19 mRNA Vaccine (nucleoside modified)COVID-19 Vaccine Moderna dispersion for injectionSpykeVax.. ..On 21-Apr-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 3 dosage form. On 08-Dec-2021, the patient experienced PYREXIA (Pyrexia) (seriousness criterion death), DROP ATTACKS (Drop attacks) (seriousness criterion death) and ATONIC SEIZURES (Drop seizures) (seriousness criterion death). The patient died on 08-Jan-2022. The cause of death was not reported. It is unknown if an autopsy was performed. . . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .Treatment information not provided..Concomitant medication not provided...Company comment: This case concerns a 83-year-old male patient, with no reported medical history, who experienced the serious, fatal, unexpected events of pyrexia, sudden death, drop attacks, and atonic seizures. The events occurred 7 months after the first dose of mRNA 1273 COVID-19 vaccine. Previously administered products to the patient includes 2 doses of mRNA 1273 COVID-19 vaccine. The patient died 8 months after the vaccine, cause of death was not reported. It is unknown if an autopsy was performed. The patient's age and long onset latency of events remain as confounders to the events. The benefit-risk relationship of mRNA 1273 vaccine is not affected by this report.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 01-Feb-2022 and was forwarded to Moderna on 01-Feb-2022. .This regulatory authority case was reported by a physician and describes the occurrence of SHOCK HAEMORRHAGIC (Hemorrhagic shock), COAGULOPATHY (Clotting disorder), MULTIPLE ORGAN DYSFUNCTION SYNDROME (Multiple organ failure), HEPATIC FAILURE (Hepatic failure), COVID-19 (SARS-CoV-2 infection) and THROMBOCYTOPENIA (Thrombopenia) in a 69-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 000105A) for COVID-19 vaccination. . .Previously administered products included for COVID-19 vaccination: Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant])COVID-19 Vaccine AstraZeneca suspension for injectionCOVID-19 Vaccine AstraZeneca on 10-May-2021 and Comirnaty BNT162b2 on 02-Aug-2021..Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant])COVID-19 Vaccine AstraZeneca suspension for injectionCOVID-19 Vaccine AstraZeneca..Concurrent medical conditions included SARS-CoV-2 infection.. ..On 07-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 09-Jan-2022, the patient experienced SHOCK HAEMORRHAGIC (Hemorrhagic shock) (seriousness criteria death, hospitalization and life threatening), COAGULOPATHY (Clotting disorder) (seriousness criteria death, hospitalization and life threatening), MULTIPLE ORGAN DYSFUNCTION SYNDROME (Multiple organ failure) (seriousness criteria death, hospitalization and life threatening), HEPATIC FAILURE (Hepatic failure) (seriousness criteria death, hospitalization and life threatening) and THROMBOCYTOPENIA (Thrombopenia) (seriousness criteria death, hospitalization and life threatening). On an unknown date, the patient experienced COVID-19 (SARS-CoV-2 infection) (seriousness criteria death, hospitalization and life threatening). The patient died on 09-Jan-2022. The reported cause of death was Multiorgan failure. An autopsy was not performed. . . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .Concomitant medication was not provided..Treatment information was not provided...Company Comment:.This case concerns a 69-year-old female patient, with relevant medical history of previous vaccination with Vaxzevria COVID-19 Vaccine and Comirnaty BNT162b2, who experienced the unexpected serious events of Shock Hemorrhagic, Coagulopathy, Multiple organ dysfunction syndrome, Hepatic failure and Thrombocytopenia. The events occurred approximately 2 days after receiving a dose of mRNA-1273 Vaccine and resulted in a fatal outcome. The unexpected serious AESI event of COVID-19 occurred on an unknown date. The reported cause of death was Multiorgan failure. An autopsy was not performed. The patient's medical history of previous vaccination with Vaxzevria COVID-19 Vaccine and Comirnaty BNT162b2, remain as confounders for the occurrence of the events. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.

Case ID	WW Identifier	Narrative Complete
[redacted]	[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 01-Feb-2022 and was forwarded to Moderna on 01-Feb-2022. .This regulatory authority case was reported by a physician and describes the occurrence of CEREBRAL INFARCTION (Middle cerebral artery infarct) and CEREBROVASCULAR ACCIDENT (Apoplectic fit) in a 47-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 045G21A) for COVID-19 vaccination. . .Previously administered products included for COVID-19 vaccination: Comirnaty BNT162b2 on 02-Jun-2021 and Comirnaty BNT162b2 on 15-Jul-2021..Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Comirnaty BNT162b2.. ..On 20-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 03-Jan-2022, the patient experienced CEREBRAL INFARCTION (Middle cerebral artery infarct) (seriousness criteria death, hospitalization and life threatening) and CEREBROVASCULAR ACCIDENT (Apoplectic fit) (seriousness criteria death, hospitalization and life threatening). The patient died on 03-Jan-2022. It is unknown if an autopsy was performed. . . .The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown.. .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .Treatment information and concomitants medications were not reported...Company comment: This case concerns a 47-year-old, female patient with no relevant medical history, who experienced the unexpected fatal AESI events of Cerebral Infarction and Apoplectic Fit. The events occurred approximately 14 days after a dose of mRNA-1273 (Moderna covid-19 vaccine) with fatal outcomes. Of note, patient previously administered two doses of covid-19 vaccine (Comirnaty BNT 162b2) prior to a dose with mRNA-1273. The rechallenge was not applicable, as the event happened after a dose of mRNA-1273 (which seems the third dose of covid-19 vaccine). Though limited information including lack of medical history, circumstances surrounding death and autopsy report was provided, this patient's previous two doses remains a contributory factor. The benefit-risk relationship of mRNA-1273 (Moderna covid-19 vaccine) is not affected by this report.
[redacted]	[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 01-Feb-2022 and was forwarded to Moderna on 01-Feb-2022. .This regulatory authority case was reported by a physician and describes the occurrence of SUDDEN DEATH (Sudden death) in a 48-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 018G21A) for COVID-19 vaccination. . .Concomitant products included TOZINAMERAN (COMIRNATY) from 23-Apr-2021 to 04-Jun-2021 for Revaccination with different COVID-19 vaccine.. ..On 15-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. The patient died on 03-Jan-2022. It is unknown if an autopsy was performed. . . .For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.. .It was reported that there was no concept of acute or chronic pathology likely to explain death...No concomitant details were provided. No treatment details were provided...Company Comment:.This is a regulatory authority case concerning a 48-year-old, male patient with a medical history concomitant product included TOZINAMERAN (COMIRNATY) from 23-Apr-2021 to 04-Jun-2021 for revaccination with different COVID-19 vaccine, who experienced the unexpected event of death. The event of death occurred approximately 19 days after a dose of mRNA-1273 (Spikevax). The medical history concomitant product included TOZINAMERAN (COMIRNATY) from 23-Apr-2021 to 04-Jun-2021 could be confounder. The event was considered related to the product per the reporter's assessment. The benefit-risk relationship of Spikevax is not affected by this report.
[redacted]	[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 01-Feb-2022 and was forwarded to Moderna on 01-Feb-2022. .This regulatory authority case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of CARDIO-RESPIRATORY ARREST (Cardio-respiratory arrest) in a 63-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. . .Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 vaccination.. .No Medical History information was reported.. .In 2021, the patient received dose of TOZINAMERAN (COMIRNATY) (Intramuscular) 1 dosage form..On 08-Dec-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 23-Dec-2021, the patient experienced CARDIO-RESPIRATORY ARREST (Cardio-respiratory arrest) (seriousness criterion death). The patient died on 23-Dec-2021. The reported cause of death was cardiorespiratory arrest. It is unknown if an autopsy was performed. . . . .Concomitant product use was not provided by the reporter. .No treatment information provided...Company Comment: This Regulatory Authority case concerns a 63 year old male , initially vaccinated with one dosage form of Tozinameran (Comirnaty) , who experienced Serious (Fatal) , unexpected event of Cardio - respiratory arrest which occurred 16 days post vaccination with the 1st dose of mRNA-1273 vaccine . The reported cause of death was cardiorespiratory arrest and it is unknown if an autopsy was done. The details surrounding this event

Case ID	WW Identifier	Narrative Complete
		was not reported. The benefit -risk relationship of mRNA -1273 (Moderna Covid 19 Vaccine) is not affected by this report.
[redacted]		This case was initially received via European Medicines Agency (Reference number: [redacted] on 01-Feb-2022. The most recent information was received on 07-Feb-2022 and was forwarded to Moderna on an unknown date. ..This regulatory authority case was reported by a physician and describes the occurrence of SUDDEN DEATH (Sudden death, cause unknown) in a 63-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 045G21A) for COVID-19 vaccination. . .Previously administered products included for COVID-19 vaccination: Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant])COVID-19 Vaccine AstraZeneca suspension for injectionCOVID-19 Vaccine AstraZeneca on 20-Apr-2021 and Comirnaty BNT162b2 on 13-Jul-2021..Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant])COVID-19 Vaccine AstraZeneca suspension for injectionCOVID-19 Vaccine AstraZeneca.. .On 12-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. The patient died on 14-Jan-2022. The cause of death was reported as unknown. It is unknown if an autopsy was performed. . ..For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .No concomitant medication information was provided...No treatment medication information was provided...Company Comment:..This regulatory authority case concerns a 63-year-old, male patient, with no reported medical history, who experienced the unexpected, serious fatal event of sudden death. The event occurred 3 days after receiving a booster dose of mRNA-1273 vaccine. The cause of death was reported as unknown. Autopsy report is not available. The patient completed primary vaccination with a different authorized or approved COVID-19 vaccines and was given a dose of AstraZeneca COVID-19 vaccine approximately 9 months and Pfizer approximately 6 months prior to mRNA-1273 vaccination with no reported adverse events. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 07-Feb-2022: Upon internal review significant correction was performed on 15-Feb-2022: It was identified that follow up document (received date: 07-Feb-2022) with reference ID [redacted] was incorrectly attached as Follow-up to this case instead of creating a new case, hence amendment created to delete the information which was related to report [redacted] (Medical history Chronic pain disorder with somatic and mental factors was deleted and event verbatim updated)
[redacted]		This case was initially received via European Medicines Agency (Reference number: [redacted] on 01-Feb-2022. The most recent information was received on 24-Mar-2022 and was forwarded to Moderna on 24-Mar-2022. .This regulatory authority case was reported by a physician and describes the occurrence of VACCINATION FAILURE (Vaccination failure) in a 76-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 300042722 & UNK and 300042722 & UNK) for COVID-19 vaccination. . .Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for Revaccination with different COVID-19 vaccine.. .The patient's past medical history included Renal transplant on 21-Apr-2021 and Aortocoronary bypass..Concurrent medical conditions included Sleep apnoea syndromes, Gout, Deafness bilateral, Venous thrombosis deep limb, Ischaemic heart disease, Dyslipidaemia, Hypertension arterial, Anterior ischaemic optic neuropathy in November 2021 and Atrioventricular block third degree.. .On 12-Feb-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 3 dosage form..On 21-May-2021, received dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 3 dosage form..On 16-Dec-2021, the patient received dose of TOZINAMERAN (COMIRNATY) (Intramuscular) 1 dosage form. On 28-Dec-2021, after starting mRNA-1273 (Spikevax), the patient experienced VACCINATION FAILURE (Vaccination failure) (seriousness criterion death). The patient died on 22-Jan-2022. The reported cause of death was pneumopathie covid-19. It is unknown if an autopsy was performed. . . .For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.. .Concomitant product use was not provided by the reporter...Dosage text was reported as 1 DF x3 total D1+D2+D3...No treatment information was provided...Company Comment: This regulatory authority case concerns a 76-year-old male patient with no relevant medical history reported, who experienced the fatal unexpected serious event of Vaccination failure which occurred 221 days after the administration of a dose of the mRNA-1273 vaccine and 12 days after the administration of Co-suspect product (non-company product) TOZINAMERAN (COMIRNATY). The patient died approximately 8 months after vaccination with mRNA-1273 and 37 days after the administration of Co-suspect product (non-company product) TOZINAMERAN (COMIRNATY). The reported cause of death was COVID-19 pneumonia. It is unknown if an autopsy was performed. The patient received the second dose 98 days after the first dose, which is not in accordance with the recommended vaccine interval. The patient was noted to have received a different brand of covid-19 vaccine from TOZINAMERAN (COMIRNATY) 6

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		months 25 days after vaccination with mRNA1273 (Interchange of vaccine products). Patients elderly age could be confounding. The benefit-risk relationship of mRNA-1273 is not affected by this report. The events were assessed as serious as per Regulatory Authority´s report.. .Most recent FOLLOW-UP information incorporated above includes:.On 24-Mar-2022: Follow-up information received included added death date (22-JAN-2022) and cause of death (COVID-19 pneumonitis), event start date corrected from 21-Dec-2021 to 28-Dec-2021, event outcome updated from NOT RECOVERED/NOT RESOLVED to FATAL and seriousness criterion updated from HOSPITALIZATION to DEATH.
[redacted]		This case was initially received via European Medicines Agency (Reference number: [redacted] on 01-Feb-2022. The most recent information was received on 09-Feb-2022 and was forwarded to Moderna on 09-Feb-2022. .This regulatory authority case was reported by a physician and describes the occurrence of PULMONARY EMBOLISM (death day after booster vaccination, sudden death; central pulmonary embolism) in a 64-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 018J21A) for COVID-19 vaccination. . .Previously administered products included for Product used for unknown indication: AstraZeneca vaccin (Vaxzevria) COVID-19 VACCIN ASTRAZENECA INJVLST on 22-Feb-2021 and AstraZeneca vaccin (Vaxzevria) COVID-19 VACCIN ASTRAZENECA INJVLST on 17-May-2021..Past adverse reactions to the above products included No adverse event with AstraZeneca vaccin (Vaxzevria) COVID-19 VACCIN ASTRAZENECA INJVLST and AstraZeneca vaccin (Vaxzevria) COVID-19 VACCIN ASTRAZENECA INJVLST.. ..On 22-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 23-Dec-2021, the patient experienced PULMONARY EMBOLISM (death day after booster vaccination, sudden death; central pulmonary embolism) (seriousness criterion death). The patient died on 23-Dec-2021. The reported cause of death was rider embolus. An autopsy was performed. The autopsy-determined cause of death was autopsy: embolism at bifurcation of pulmonary blood vessels, additional finding: mild pneumonitis and in an otherwise cardiac compromised condition with foci of scarred old infarction and recent infarction and mild manifestations of left failure and right failure. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 31-Dec-2021, Autopsy: abnormal Final Pathological Anatomical Diagnoses: 1. Hypertrophic heart (594 gr) with old and recent microscopic infarction and replacement fibrosis in patent coronaries. a. Pulmonary picture of acute and chronic congestion, incomplete picture of congestive vasculopathy, appropriate to left failure. b. Liver with an image of acute - and subtle signs of chronic right failure. 2. Lungs with a. Central pulmonary embolism, recent thrombus. No manifestations of longer existing thromboembolic events (but does not exclude this possibility). b. Mild and focal pneumonitis It concerns a 64-year-old man with a blank history. Found dead by the partner. No complaints in the previous days. The day before the death, the patient received a booster for COVID-19. Death is explained by a central pulmonary embolism based on recent thrombosis in an otherwise cardiac compromised condition with foci of scarred, old infarcer and recent infarction and mild manifestations of left failure and right failure. Additional finding is focal, mild pneumonitis, not appropriate to the aforementioned diagnoses but may be explained on the basis of experienced respiratory infection (or possibly underlying autoimmune disease). A relationship between pneumonitis and possible candidal esophagitis is speculative and cannot be substantiated by intraalveolar abnormalities. Both this pneumonitis and cardiac compromised condition as a booster vaccination can basically contribute to thrombotic diathesis. A unique causal contribution from booster vaccination is not to be demonstrated or excluded with certainty., abnormal Internal examination and microscopy: Tractus circulatorius: Hypertrophic heart (594 gr) with normal aspect of a mobile pericard with a trace of bright yellow pericardial fluid, no fibrin seizure. Some pale paved plaques on the truncus pulmonalis and the opposite pericard, microscopic fibrohyaline plaques with focal calcification. Plaques truncus pulmonalis: fibrohyaline plaques with no picture of calcification. The aortic arch shows normal, patent branches of the truncus brachiocephalicus, carotid communis left and subclavian left. Moderate generalized atherosclerotic changes at the level of the thoracic and abdominal aorta and branches. Coronaries are patent, with minor atherosclerotic changes. At cut, ventricles are normally contraindicated and with some heterogenicity in the LDH staining corresponding to a restricted zone of lymphocytic infiltrate amid extinct myocytes in the left ventricular sidewall, appropriate to a picture of recent infarction, without lecture and position (advanced on clean response, estimated a few weeks old). Furthermore multifocal microscopic myofibrosis with compensatory hypertrophy of myocytes in all walls of both the left and right ventricles. The septum also shows microscopic myofibrosis with high-fat metaplasia. Mild calcifications of the valve blades without further macroscopic abnormalities., abnormal Tractus digestivus? Liver (2172 gr): dilatation of central venules and pericentral sinusoids with subtle pericentral increase in collagen, focal fluttering in the surrounding parenchyma, as signs of chronic right ventricular decompensation. Patent bile ducts. Liver with a smooth haircut, parenchyma without macroscopic peculiarities. No ascites, no peripheral edema. - Proximal esophagus with extensive

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		white batter, suspected for candidal esophagitis, but without detectable yeasts (limited assessable tissue). Stomach and duodenum with a dark mucosa without further abnormalities. Superior of the proximal duodenum and proximal jejunum shows some white deposits on the serosal side: foci of fat necrosis. Pancreas not microscopically assessed by autolysis. - Gallbladder, appendix and colon without macroscopic abnormalities, microscopic assessment limited by autolysis. Genitourinary tractus: Left kidney with a slightly granular surface. Both kidneys contain some small kidney stones. Microscopic no significant abnormalities. Patent ureters, no signs of tribe. Dark bladder mucosa. Right kidney and prostate without macroscopic abnormalities. Endocrinological tract: Adrenal, pancreas and thyroid without abnormalities. Hematological traction: Spleen without macroscopic abnormalities. Lymph nodes from station 7 normal arrangement and buildup of follicles with the presence of star celestial macrophages. Neurological: Brains have been extracted. No signs of bleeding or other macroscopically visible abnormalities were observed. Further research follows after fixation. and abnormal Internal examination and microscopy:Lungs (Left 956 grams, right: 1058 grams) with signs of acute and chronic thrust: zones with pulmonary edema, propelled capillaries in alveolar septa, lymphangiectasis and focal iron deposits on elastin fibers of venules observed. Some arterialization of veins appropriate to congestive vasculopathy, however, incomplete picture with minimal re-modeling of the pulmonary arteries. Central to the bifurcation of the aa pulmonales is a large, pale convolute, filling the lumen and a length of several centimeters, microscopically consisting of a well-formed fibrin network with captured erythrocytes. No organization in the sense of endothelial growth and recanalization. To be referred to as pulmonary embolism, recent thrombus (not reliable to date). Further fairly patent pulmonary vessels. No infarction, no fatty streaks or intimafibrosis in the pulmonary arteries. NB The lack of characteristics of thrombotic arteriopathy rather does not exclude thromboembolic lesions. In addition, a mild pneumonitis picture with patchy spread of lymphocytic infiltrates (predominantly T-lymphocytes with focal beginning follicle formation) in the alveolar interstitium without expansion of the marginal zone, most prominent in the lower lobes on the one hand. Bright yellow pleural moisture on the sides, 50 mL on the left and a trace on the right. Free lumina of trachea and main bronchi with red discoloration of the mucosa. Some anthracosis deposition on both lungs, smooth surface... . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .Concomitant medications details were not reported by the reporter..Treatment details was not reported by the reporter...Company Comment:.This regulatory authority case concerns a 64-year-old male patient with no medical history reported who experience
[redacted]	[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 02-Feb-2022 and was forwarded to Moderna on 02-Feb-2022. .This regulatory authority case was reported by a consumer and describes the occurrence of SUDDEN DEATH (Death on 18.12.21) in a 70-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. . .Patient had high blood pressure on 05.08.1951. .Previously administered products included for Prophylactic vaccination: Comirnaty and COVID-19 Vaccine AstraZeneca..Past adverse reactions to the above products included No adverse event with COVID-19 Vaccine AstraZeneca and Comirnaty.. ..On 29-Nov-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. The patient died on 18-Dec-2021. The cause of death was not reported. It is unknown if an autopsy was performed. . . . .No concomitant medications were reported..No treatment medications were reported...Company comment:.This Regulatory authority case concerns a 70-year-old, female patient, with medical history of hypertension, who experienced the unexpected, serious (fatal) event of sudden death. The event occurred 19 days after receiving a dose of mRNA-1273 vaccine, considered as the third dose of the patient COVID-19 vaccination schedule as she previously received a dose of AstraZeneca's COVID-19 vaccine and another of Cominarty's COVID-19 vaccine. The cause of death was reported as unknown. Autopsy report is not available. No further clinical information was provided for medical reviewing. The medical history of hypertension remains as a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
[redacted]	[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 02-Feb-2022 and was forwarded to Moderna on 02-Feb-2022. .This regulatory authority case was reported by a consumer and describes the occurrence of SUDDEN DEATH (just dropped and dead. Suddenly and unexpectedly.) in a 67-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004951) for COVID-19 vaccination. . .Previously administered products included for Prophylactic vaccination: Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant])COVID-19 Vaccine AstraZeneca suspension for injectionCOVID-19 Vaccine AstraZeneca on 21-Apr-2021 and Comirnaty BNT162b2 on 14-Jul-2021..Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant])COVID-19 Vaccine AstraZeneca suspension for injectionCOVID-19 Vaccine AstraZeneca.. ..On 13-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax)

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		(unknown route) 1 dosage form. The patient died on 16-Dec-2021. The cause of death was not reported. It is unknown if an autopsy was performed. . . . . .Concomitant product use was not provided by the reporter..Reporter reported pre-existing illnesses on 2013, bypass at Herzen. Blood thinner, last analysis at cardiologist inconspicuous. After the first two vaccinations, a few days of rest and then it went back...Treatment medication was not provided by the reporter...Company comment:.This Regulatory authority case concerns a 67-year-old, male patient, with medical history of Obesity (Body mass index 39.63) and unspecified bypass, who experienced the unexpected, serious (fatal) event of sudden death. The event occurred 3 days after receiving a dose of mRNA-1273 vaccine, considered as the third dose of the patient COVID-19 vaccination schedule as he previously received as first dose an AstraZeneca's COVID-19 vaccine and as second a Cominarty's COVID-19 vaccine. The cause of death was reported as unknown. Autopsy report is not available. No further clinical information was provided for medical reviewing. The medical history of Obesity (Body mass index 39.63) and unspecified bypass remains as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
[redacted]		This case was initially received via European Medicines Agency (Reference number: [redacted] on 01-Feb-2022. The most recent information was received on 14-Feb-2022 and was forwarded to Moderna on 14-Feb-2022. .This regulatory authority case was reported by a consumer and describes the occurrence of PNEUMONIA (Then his lungs were full and had pneumonia.) in an 84-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. . .The patient's past medical history included Pulmonary embolism (Family history: False), Arrhythmia (Family history: False), Pneumonia (Family history: False) and Pulmonary edema (Family history: False)..Previously administered products included for Product used for unknown indication: COMIRNATY (BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST) on 12-Feb-2021, COMIRNATY (BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST) on 26-Mar-2021..Past adverse reactions to the above products included No adverse reaction with COMIRNATY and COMIRNATY..Concurrent medical conditions included Esophageal cancer metastatic (Family history: False)..Concomitant products included BROTIZOLAM (LENDORMIN), OXYCODONE HYDROCHLORIDE (OXYCODON), ASCORBIC ACID, FOLIC ACID, IRON PIDOLATE (B IJZER NUTRIDOSES), ANTICOAGULANT CITRATE DEXTROSE and CODEINE SULFATE (CODEINE SULPHATE) for an unknown indication.. ..On 29-Nov-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 01-Dec-2021, after starting mRNA-1273 (Spikevax), the patient experienced PNEUMONIA (Then his lungs were full and had pneumonia.) (seriousness criterion death). The patient died on 08-Dec-2021. The reported cause of death was longontsteking. An autopsy was not performed. . . . .No treatment information was provided...Company Comment: This regulatory case concerns an 84-year-old, male patient with the concurrent condition of metastatic esophageal cancer and past medical history of pulmonary embolism, pulmonary edema and arrhythmia, who experienced the unexpected, fatal event of Pneumonia. The event occurred 2 days after a dose of mRNA-1273 vaccine. It should also be noted that the patient received 2 doses of Tozinameran COVID-19 vaccine approximately 8 months prior to the mRNA-1273 (Interchange of vaccine products). Clinical course leading to demise and treatment details were not provided. The patient died 10 days post-vaccination. Autopsy was not performed in this case. The elderly age of the patient and concurrent metastatic malignancy remain as confounders for the event. Additionally, the elderly age and malignant condition along with history of pulmonary embolism, pulmonary edema and arrhythmia could have contributed to the fatal outcome. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report.. .Most recent FOLLOW-UP information incorporated above includes:.On 14-Feb-2022: Significant follow-up included suspect batch number removed. Concomitant drugs updated.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 02-Feb-2022 and was forwarded to Moderna on 02-Feb-2022. .This regulatory authority case was reported by a physician and describes the occurrence of CEREBRAL HAEMORRHAGE (Hemorrhage intracerebral) in a 56-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000120A) for COVID-19 vaccination. . .Previously administered products included for COVID-19 vaccination: COMIRNATY on 14-Jul-2021 and COMIRNATY on 28-Aug-2021..Past adverse reactions to the above products included No adverse event with COMIRNATY and COMIRNATY.. ..On 04-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 05-Jan-2022, the patient experienced CEREBRAL HAEMORRHAGE (Hemorrhage intracerebral) (seriousness criteria death, hospitalization and life threatening). The patient died on 09-Jan-2022. The reported cause of death was Haemorrhage intracerebral. It is unknown if an autopsy was performed. . . .For mRNA-1273 (Spikevax)

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		(Unknown), the reporter did not provide any causality assessments.. .No concomitant and treatment medications were reported...Company Comment: This regulatory case concerns a 56-year-old, male patient with history of administration of two doses of Comirnaty (Pfizer/BioNTech COVID-19 mRNA vaccine), who experienced the unexpected, serious AESI of cerebral haemorrhage. The event, which was life-threatening, resulted in hospitalization and resulted in a fatal outcome, occurred 1 day after administration of the booster dose of the Moderna mRNA-1273 vaccine. The report stated that the patient expired on 09Jan2022. It was unknown if an autopsy was done. However, intracerebral haemorrhage was reported as the cause of death. No further details were provided. The history of administration of two doses of Comirnaty (Pfizer/BioNTech COVID-19 mRNA vaccine) remains a confounder. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report.
[redacted]		This case was initially received via European Medicines Agency (Reference number: [redacted] on 01-Feb-2022. The most recent information was received on 24-Jun-2022 and was forwarded to Moderna on 24-Jun-2022. .This regulatory authority case was reported by a consumer and describes the occurrence of DYSARTHRIA (could no longer talk and swallow due to infarction), CEREBRAL INFARCTION (Next day cerebral stroke), DYSPHAGIA (could no longer talk and swallow due to infarction), PNEUMONIA (could no longer talk and swallow due to the infarction, developed pneumonia) and CEREBRAL INFARCTION (Another cerebral stroke) in an 84-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 093F21A) for COVID-19 immunisation. The occurrence of additional non-serious events is detailed below. . .The patient's past medical history included Fall (Fell on her hip, hospitalised for that. Years ago), Urinary bladder polyp (hospitalisation), Breast cancer (hospitalised for breastcancer when she was 50 years old) in 1987, Claudication (treatment: advice to walk, which she did, until she died, targetting 10000 steps per day. In addition acetylsalicylic acid. In 2016 stent placement in her legs) in 2004, Cataract in 2013, Urogenital prolapse (Prolapse uterus and bladder wv, manchesterplastic and back wall plastic) in 2002, Hypertension, Cognitive impairment (mild cognitive impairment) and Stent placement (placing stents in her\ legs (2016)) in 2016..Previously administered products included for Product used for unknown indication: BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST on 26-Feb-2021, BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST on 02-Apr-2021..Past adverse reactions to the above products included Confusion with BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST; and No adverse event with BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST..Concurrent medical conditions included Allergy (Rest)..Concomitant products included ACETYLSALICYLZUUR for Claudication, METOPROLOL SUCCINATE (METOPROLOL SUCCINAT BETA) and CHLOORTALIDON for Hypertension, PAROXETINE (PAROXETIN [PAROXETINE]) for Seasonal depression.. ..On 12-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 12-Dec-2021, the patient experienced LOSS OF CONSCIOUSNESS (Has had a walk away the same day in the evening). On 13-Dec-2021, after starting mRNA-1273 (Spikevax), the patient experienced CEREBRAL INFARCTION (Next day cerebral stroke) (seriousness criteria death and hospitalization). On 14-Dec-2021, the patient experienced DYSARTHRIA (could no longer talk and swallow due to infarction) (seriousness criteria death and hospitalization), DYSPHAGIA (could no longer talk and swallow due to infarction) (seriousness criteria death and hospitalization), PNEUMONIA (could no longer talk and swallow due to the infarction, developed pneumonia) (seriousness criteria death and hospitalization) and CEREBRAL INFARCTION (Another cerebral stroke) (seriousness criteria death and hospitalization). The patient died on 17-Dec-2021. The reported cause of death was cerebral infarction (primary cause of death) and Pneumonia. An autopsy was not performed. At the time of death, LOSS OF CONSCIOUSNESS (Has had a walk away the same day in the evening) had resolved. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.In 2021, Blood cholesterol: last measurement of 2021 was 3.6 Annual measurements since 2010 show that total cholesterol was always slightly elevated: between 5.4 and 6.4 (normal =<5), last value in 2021 was 5.9. HDL cholesterol was always tidy: between 1.7 and 2.2. LDL cholesterol, however, usually above the norm (<3= normal) between 2.9-4. Last measurement of 2021 was 3.6. Ratio always neatly below 5. Triglycerides also normal..In 2021, Blood pressure measurement: 140/80 Her blood pressure according to the general practitioner's file 2015:156/81 2016:154/91 2017:163/83 2018:147/81 2019:128/82 2020:130/72 2021:140/80. very adherence to both means to lower blood pressure...In 2021, Mini mental status examination: 27/30 27/30 test_result_lowest_range : 25 test_result_highest_range : 30..In 2021, Montreal cognitive assessment: 23/30 23/30 test_result_lowest_range : 26 test_result_highest_range : 30..On 13-Dec-2021, Scan: occlusion of the

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		a. vertebralis on the one hand occlusion of the a. vertebralis on the one hand, without evidence of atrial fibrillation.. . . . .Company Comment: This regulatory case concerns an 84-year-old female patient, with relevant medical history of hypertension, breast cancer, cognitive impairment, claudication of legs s /p stent placement, who experienced the unexpected serious and fatal events of Cerebral infarction (AESI) (reported 2 episodes), Dysarthria, Dysphagia, and Pneumonia. The event Cerebral infarction (next day cerebral stroke) occurred 1 day, and events Cerebral infarction (another cerebral stroke), Dysarthria, Dysphagia, and Pneumonia occurred 2 days, respectively, after receiving the dose of mRNA-1273 vaccine. The events were reported along with the non-serious loss of consciousness that happened same day post vaccination. Scan showed occlusion of the a. vertebralis on the one hand, without evidence of atrial fibrillation. The following tests were done on an unspecified date (units not reported): total cholesterol 5.9, HDL cholesterol between 1.7 and 2.2, LDL cholesterol 3.6, and triglycerides normal, blood pressure 140/80, mini mental status examination 27/30, and montreal cognitive assessment 23/30. Clinical course of hospitalization and treatment details were not reported. The patient died 5 days post vaccination. The causes of death were reported as Cerebral infarction as the primary cause and Pneumonia. Autopsy was not performed. Patient received 2 doses of Tozinameran vaccine at an interval of 35 days with reported adverse event of confusion with the 2nd dose, and the 2nd dose was given 8 months and 10 days prior to the mRNA-1273 vaccine (Interchange of vaccine products noted). The medical history of hypertension, breast cancer, and claudication could be considered as risk factors for the event cerebral infarction. Cognitive impairment as contributory factor for the event dysarthria. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report.. .Most recent FOLLOW-UP information incorporated above includes:.On 24-Jun-2022: Medical history added, Lab tests added, event verbatim updated.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 03-Feb-2022 and was forwarded to Moderna on 03-Feb-2022. .This regulatory authority case was reported by a physician and describes the occurrence of CARDIO-RESPIRATORY ARREST (Cardiorespiratory arrest), PULMONARY THROMBOSIS (Thrombosis pulmonary) and THROMBOCYTOPENIA (Thrombocytopenia) in a 48-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. . .Concurrent medical conditions included Obesity, Sleep apnea (treated with forced respiratory pressure CPAP), Thrombosis venous deep (Treated with Lixiana (endoxaban)27/05/2021 Ecodoppler control for DVT 2020: residual popliteal thrombosis with preserved flow) in 2020, Factor V Leiden mutation and Migraine..Concomitant products included TOZINAMERAN (COMIRNATY) for COVID-19 vaccination, EDOXABAN TOSILATE (LIXIANA) for Thrombosis venous deep.. ..On 29-Dec-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On 07-Jan-2022, the patient experienced CARDIO-RESPIRATORY ARREST (Cardiorespiratory arrest) (seriousness criteria death, hospitalization and life threatening), PULMONARY THROMBOSIS (Thrombosis pulmonary) (seriousness criteria death, hospitalization and life threatening) and THROMBOCYTOPENIA (Thrombocytopenia) (seriousness criteria death, hospitalization and life threatening). The patient died on 08-Jan-2022. An autopsy was performed, but no results were provided. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 07-Jan-2022, Fibrin D dimer: 69000 (High) 69000 microgram per millilitre..On 07-Jan-2022, Platelet count: 134 (Low) 134 thousand per microlitre..On 07-Jan-2022, Prothrombin time: 17.8 (High) 17.8 s.. . .mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on 29-Dec-2021.. .For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.. .No treatment medications provided by the reporter...Company comment:.This case concerns a 48-year-old male patient with relevant medical history of Thrombosis venous deep, Obesity and Factor V Leiden mutation who experienced serious unexpected events of Cardio-respiratory arrest, Pulmonary thrombosis and Thrombocytopenia and subsequently died. The events occurred 10 days after the first dose of mRNA-1273. The patient died the following day. Autopsy was performed, however, the results were not provided. Causality is confounded with patient's reported medical history and concomitant use of Tozinameran. The benefit-risk relationship of mRNA-1273 is not affected by this report. Interchange of vaccine products should have been considered in this particular case as the patient also received Tozinameran. It should be noted that it was reported that the patient received first dose of the Company product at the dose of 0.25 ml. This information was retained as such.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 04-Feb-2022 and was forwarded to Moderna on 04-Feb-2022. .This regulatory authority case was reported by a physician and describes the occurrence of CARDIAC ARREST (Asystolia), ACUTE CORONARY SYNDROME (Non ST segment elevation acute coronary syndrome) and BRAIN INJURY (Hypoxic brain damage) in a 47-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004500) for COVID-19 vaccination. . .Previously administered products

Case ID	WW Identifier	Narrative Complete
		included for COVID-19 vaccination: COMIRNATY on 27-May-2021 and COMIRNATY on 01-Jul-2021..Past adverse reactions to the above products included No adverse event with COMIRNATY and COMIRNATY.. ..On 23-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 08-Jan-2022, the patient experienced CARDIAC ARREST (Asystolia) (seriousness criteria death, hospitalization, medically significant and life threatening), ACUTE CORONARY SYNDROME (Non ST segment elevation acute coronary syndrome) (seriousness criteria death, hospitalization, medically significant and life threatening) and BRAIN INJURY (Hypoxic brain damage) (seriousness criteria death, hospitalization, medically significant and life threatening). The patient died on 10-Jan-2022. It is unknown if an autopsy was performed. . . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .No concomitant medications were reported...No treatment medications were reported...COMPANY COMMENT : This regulatory case concerns a 47-year-old, male patient with no relevant medical history, who experienced the unexpected serious AESI event of acute coronary syndrome and unexpected serious events of cardiac arrest, brain injury events occurred 16 days after administration of third dose of the Moderna mRNA-1273 vaccine . The patient was noted to have received 2 doses from TOZINAMERAN (COMIRNATY) 4 months prior to current vaccination with mRNA1273 (Interchange of vaccine products). The patient died on 10-Jan-2022. It is unknown if an autopsy was performed. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report. . The events were assessed as serious as per Regulatory Authority's report due to important medical condition, hospitalization ,life threating ,hospitalization.
[redacted]		This case was received via European Medicines Agency (Reference number [redacted]) on 07-Feb-2022 and was forwarded to Moderna on 07-Feb-2022. .This regulatory authority case was reported by a pharmacist and describes the occurrence of CEREBROVASCULAR ACCIDENT (Stroke), HEMIPARESIS (Hemiparesis) and CEREBRAL INFARCTION (Cerebral infarction) in an 80-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 092F21A) for COVID-19 vaccination. . .Previously administered products included for COVID-19 vaccination: Comirnaty BNT162b2 on 28-Apr-2021 and Comirnaty BNT162b2 on 09-Jun-2021..Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Comirnaty BNT162b2..Concurrent medical conditions included Atrial fibrillation.. ..On 17-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 03-Jan-2022, the patient experienced CEREBROVASCULAR ACCIDENT (Stroke) (seriousness criteria death, hospitalization and life threatening), HEMIPARESIS (Hemiparesis) (seriousness criteria death, hospitalization and life threatening) and CEREBRAL INFARCTION (Cerebral infarction) (seriousness criteria death, hospitalization and life threatening). The patient died on 04-Jan-2022. It is unknown if an autopsy was performed. . . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .Concomitant Medication use information was not provided by reporter..Treatment Medication use information was not provided by reporter...Company comment:.This Fatal Regulatory Authority case concerns a 80-year-old, male patient, with medical history of atrial fibrillation, who experienced the unexpected, serious (death/ life threatening/ hospitalization) and AESI of Cerebrovascular accident and cerebral infarction, among others. The events occurred approximately 27 days after receiving a dose of mRNA-1273 vaccine, considered as the third dose of the patient's COVID-19 vaccination schedule, as he received previously two doses of Cominarty's COVID-19 vaccine as first and second doses. The patient died the day after the events developed. Cause of death was reported as unknown. Autopsy report is not available. The medical history of atrial fibrillation remains as a confounder. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.
[redacted]		This case was received via Takeda Pharmaceuticals (Reference number: [redacted] on 04-Feb-2022 and was forwarded to Moderna on 08-Feb-2022. .This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by an anatomist, was received via the PMDA (Ref, [redacted]. The patient had a history of uterine cancer, rectal cancer, and metastases to lymph nodes and was taking tegafur/uracil. On 25-Apr-2021, the patient received the 1st dose of SARS-CoV-2 vaccine (coronavirus modified uridine RNA vaccine made by Pfizer). On 16-May-2021, the patient received the 2nd dose of SARS-CoV-2 vaccine (coronavirus modified uridine RNA vaccine made by Pfizer). On 31-Jan-2022, at 11:15, the patient received the 3rd dose of the vaccine. After the vaccination, the patient less energetic than usual and looked sleepy. On 02-Feb-2022, at 00:00, the patient was confirmed dead. In the morning, the patient was found dead in the bathtub of her bathroom. The cause of death was considered as drowning. The outcome of lack of energy and sleepy looking was unknown. Follow-up investigation will be made. .LP Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship...Company comment:.This case concerns a 77-year-old female patient with relevant medical history of uterine cancer, rectal cancer, and metastases to lymph nodes who experienced

Case ID	WW Identifier	Narrative Complete
		serious unexpected event of Drowning and non-serious unexpected events of Listless and Somnolence. The events Listless and Somnolence occurred on the same day after the third dose of mRNA-1273. Furthermore, two days following the vaccination the patient was confirmed dead. It was reported that in the morning, the patient was found dead in the bathtub of her bathroom. The cause of death was considered as drowning. It is unknown if an autopsy was performed. The outcome of the remaining events was unknown. No further information was provided. Causality is confounded with patient's advanced age and reported medical history. The Reporter considered the events as possibly related to the Company product. The benefit-risk relationship of mRNA-1273 is not affected by this report. Interchange of vaccine products should have been considered in this particular case as the patient received Pfizer vaccine prior to company product.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 07-Feb-2022 and was forwarded to Moderna on 07-Feb-2022. .This regulatory authority case was reported by a physician and describes the occurrence of COVID-19 IMMUNISATION (1st and 2nd dose Comirnaty, 3rd dose Moderna), CHEST PAIN (Complaint of chest pain on the night of death) and DEATH (Complaint of chest pain on the night of death) in a 46-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. . .No history and no treatment and no allergy - No risk factor. .Previously administered products included for Drug use for unknown indication: COMIRNATY in May 2021 and COMIRNATY in June 2021..Past adverse reactions to the above products included No adverse event with COMIRNATY and COMIRNATY.. ..On 02-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, the patient experienced COVID-19 IMMUNISATION (1st and 2nd dose Comirnaty, 3rd dose Moderna) (seriousness criterion death) and CHEST PAIN (Complaint of chest pain on the night of death) (seriousness criterion death). The patient died on 03-Dec-2021. It is unknown if an autopsy was performed. . . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .Concomitant product use was not provided by the reporter...Company comment:.This Fatal Regulatory Authority case concerns a 46-year-old, male patient, with no reported medical history, who experienced the unexpected, serious (death) events of Chest pain and death. Revaccination with different COVID-19 vaccine was also reported, as the patient received as first and second dose of his COVID-19 vaccination schedule two doses of Cominarty's vaccine. Time to onset from vaccination was not reported for the event chest pain. The patient died 1 day after receiving a dose of mRNA-1273 vaccine, considered as the third dose. Cause of death was reported as unknown. Autopsy report is not available. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 07-Feb-2022 and was forwarded to Moderna on 07-Feb-2022. .This regulatory authority case was reported by a health care professional and describes the occurrence of FOETAL EXPOSURE DURING PREGNANCY (Foetal exposure during pregnancy, first trimester, GA 5 weeks), CONGENITAL CENTRAL NERVOUS SYSTEM ANOMALY (Suspicion of posterior fossa malformation), COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine), CONGENITAL CARDIOVASCULAR ANOMALY (Congenital cardiovascular anomaly NOS) and HYDRONEPHROSIS (Two kidneys with hydronephrosis and tapered echogenic renal parenchyma bilaterally) in a foetus of an unknown age and gender exposed to mRNA-1273 (Spikevax) (batch no. 3004959) , while the mother received the product for COVID-19 vaccination. . .MEDICAL HISTORY (Parent): Previously administered products included for COVID-19 immunisation: COVID-19 VACCINE JANSSEN on 12-Jun-2021..Past adverse reactions to the above products included No adverse reaction with COVID-19 VACCINE JANSSEN.. .No Medical History information was reported.. ..On 06-Oct-2021, the mother received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. Last menstrual period and estimated date of delivery were not provided. In November 2021, the foetus was diagnosed with CONGENITAL CENTRAL NERVOUS SYSTEM ANOMALY (Suspicion of posterior fossa malformation) (seriousness criteria death and congenital anomaly), CONGENITAL CARDIOVASCULAR ANOMALY (Congenital cardiovascular anomaly NOS) (seriousness criteria death and congenital anomaly) and HYDRONEPHROSIS (Two kidneys with hydronephrosis and tapered echogenic renal parenchyma bilaterally) (seriousness criteria death and congenital anomaly). On an unknown date, the foetus was diagnosed with FOETAL EXPOSURE DURING PREGNANCY (Foetal exposure during pregnancy, first trimester, GA 5 weeks) (seriousness criteria death and congenital anomaly) and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) (seriousness criteria death and congenital anomaly). The Foetus was exposed to mRNA-1273 (Spikevax) beginning around the fifth week of the pregnancy..The delivery occurred on 08-Dec-2021, which was reported as Elective Termination..For foetus 1, The outcome was reported as Elect Termination w Cong Anomaly. The foetus died on 08-Dec-2021. The reported cause of death was Induced abortion. An autopsy was not

Case ID	WW Identifier	Narrative Complete
		performed. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.In 2021, Prenatal screening test: array-cgh (normal) (normal) Array-CGH (normal)..In November 2021, Ultrasound antenatal screen: multiple anomalies Gestation period 12+2 seen multiple anomalies:, neck edema of 8 mm, Neck edema of 8 mm, generalized subcutaneous edema, echogenic intestines Echogenic intestines, normally a 4-chamber image of the heart There's normally a 4-chamber image of the heart, two kidneys with hydronephrosis Two kidneys with hydronephrosis, produce normal outflow. thus only a large vessel produce normal outflow. thus only a large vessel, small but visible bladder Small but visible bladder, minor amnion fold seen all the way down Minor amnion fold seen all the way down, a broad aorta. a broad aorta., cns is seen with fossa posterior malformation CNS is seen with fossa posterior malformation., three-vessel section in the three-vessel section, which may represent, tapered echogenic renal parenchyma bilaterally tapered echogenic renal parenchyma bilaterally, but was not able to but was not able to and other fetal anatomy is estimated nothing abnormal Other fetal anatomy is estimated nothing abnormal.. . .For mRNA-1273 (Spikevax) (Transplacental), the reporter did not provide any causality assessments.. .Gestation period when reaction/event was observed in the foetus was 12 weeks.No concomitant and treatment medications were reported...Company comment: This regulatory authority case of fetal exposure during pregnancy concerns a 12-week fetus, with a 36-year-old mother with previous JANSSEN COVID-19 vaccine, who experienced the serious (fatal, congenital anomaly) unexpected events of congenital central nervous system anomaly, congenital cardiovascular disorder and hydronephrosis. Fetus was exposed to mRNA 1273 COVID-19 Vaccine at 5 weeks gestation. The month after fetal nuchal translucency ultrasound showed fetus (12+2 weeks gestation) with multiple anomalies namely, generalized subcutaneous edema, two kidneys with hydronephrosis, a broad aorta, and CNS was seen with posterior fossa malformation, no other fetal abnormality noted. Array CGH was normal. Mother had elective termination of pregnancy with congenital anomaly and underwent induced abortion. An autopsy was not performed. Event COVID-19 immunisation, revaccination with different COVID-19 vaccine was also reported by the Regulatory authority as mother received different brands of COVID-19 vaccine. The mother receiving a different COVID-19 vaccine, JANSSEN, remain as confounder. The benefit-risk relationship of mRNA 1273 vaccine is not affected by this report.
[redacted]		This case was received via Takeda Pharmaceuticals (Reference number: [redacted] on 07-Feb-2022 and was forwarded to Moderna on 09-Feb-2022. ..This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a (physician), was received via the PMDA (Ref, [redacted]. ..The patient was confined to a wheelchair.The patient had deformed feet due to rheumatism and had a history of surgery. ..On 22-Jun-2021, the patient received the 1st dose of SARS-CoV-2 vaccine (coronavirus modified uridine RNA vaccine made by Pfizer). ..On 13-Jul-2021, the patient received the 2nd dose of SARS-CoV-2 vaccine (coronavirus modified uridine RNA vaccine made by Pfizer). After the vaccination, pyrexia developed. On an unknown date, body temperature before the vaccination: 36 degrees Celsius. ..On 03-Feb-2022, at 13:30, the patient received the 3rd vaccination with this vaccine. Thereafter, there were no changes in the patient's condition. ..On 04-Feb-2022, around 11:30, pyrexia of 39.0-39.9 degrees Celsius developed. The patient took acetaminophen. Around 12:00, the patient had somnolence. At 14:45, the patient experienced decreased consciousness and cardio-respiratory arrest. At 16:05, resuscitation was performed, and spontaneous circulation returned. The patient was hospitalized with a respirator. ..On 05-Feb-2022, at 00:13, the patient died. ..The outcome of pyrexia, decreased consciousness, and cardiac-respiratory was unknown. ..Follow-up investigation will be made. ..Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
[redacted]		This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 03-Feb-2022. The most recent information was received on 14-Mar-2022 and was forwarded to Moderna on 22-Mar-2022. . This case was reported by a physician via a medical representative. On 05-Feb-2022, follow-up information, reported by a physician, was received by Takeda via Moderna's adverse reaction reporting site([redacted]). On 07-Feb-2022, follow-up information, reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, [redacted]. On 14-Mar-2022, follow-up information was received from a physician. Respiratory arrest and no response to calls were assessed as serious by the MAH. On 18-Jun-2021, the patient received the 1st dose of coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 09-Jul-2021, the patient received the 2nd dose of coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 21-Jan-2022, at 13:00, the patient received the 3rd dose of this vaccine. On 24-Jan-2022, after 15:00, pyrexia of 38.9 degrees Celsius with chills was noted. No respiratory symptoms, digestive symptoms, or swollen joints were observed. The patient took 2 tablets of acetaminophen 200 mg and was followed up. On 25-Jan-2022, in the morning, the temperature decreased to 36.8 degrees Celsius. Since then, there was no chills or pyrexia, and the patient was followed up. Blood test on the same day showed white blood cells of 20,900 with Neu of

Case ID	WW Identifier	Narrative Complete
		78.0%, CRP of 11.4, NTproBNP of 9,333, Alb of 1.9, GOT of 30, GPT of 23, Na of 128, K of 4.4,and Cl of 95. On 26-Jan-2022, at 02:55, the body temperature was 36.7 degrees Celsius. The patient was awake and responded to calls. At 04:00, the patient did not respond to voice calls, and symptoms of complexion ill and feeling cold were found. The patient was found in a state of respiratory arrest, and the nurse was notified. At 06:45, the patient was confirmed as dead. The cause of death was unknown. No autopsy was performed. The outcome of chills, no response to calls, complexion ill, feeling cold, and respiratory arrest was unknown. The outcome of pyrexia was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: The symptom developed on 22-Jan-2022 after vaccination with this vaccine, and the patient died on 26-Jan-2022; therefore, a temporal association between the occurrence of adverse events and the timing of administration of this vaccine cannot be ruled out. Since the patient was continuing to take medications prescribed by the previous physician prior to admission, the occurrence of adverse events was not associated with the concomitant drugs. The occurrence of adverse events is not related to pathological factors of underlying diseases and complications. The symptoms developed on the fifth day after vaccination with this vaccine, and considering the patient's condition before the vaccination, it is suspected that the symptoms were related to the vaccination. However, on 26-Jan-2022, the day of death, when the patient was examined at 02:55, the body temperature was 36.7 degrees Celsius, and the patient was awake and responded to calls. At 04:00, at the visit for examination, the patient was found in a state of respiratory arrest, so the relationship between the death and this vaccine is unknown. Follow-up received on 14-MAR-2022 Updated: Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
[redacted]		This case was initially received via European Medicines Agency (Reference number: [redacted] on 07-Feb-2022. The most recent information was received on 07-Mar-2022 and was forwarded to Moderna on 07-Mar-2022. .This regulatory authority case was reported by a physician and describes the occurrence of SHOCK (acute on chronic renal failure requiring dialysis, shock, anasarcatic congestive state, cardiomegaly), ACUTE KIDNEY INJURY (acute on chronic renal failure requiring dialysis, shock, anasarcatic congestive state, cardiomegaly), CARDIOMEGALY (acute on chronic renal failure requiring dialysis, shock, anasarcatic congestive state, cardiomegaly) and GENERALISED OEDEMA (acute on chronic renal failure requiring dialysis, shock, anasarcatic congestive state, cardiomegaly) in a 77-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3005887) for COVID-19 vaccination. . .The patient's past medical history included Gallbladder stones, Acute myeloid leukaemia on 01-Jan-1993, Humerus fracture and Stroke on 01-Jul-2017..Previously administered products included for SARS-CoV-2 immunisation: COMIRNATY (COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03)) on 25-Mar-2021 and COMIRNATY (COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03)) on 14-Apr-2021..Past adverse reactions to the above products included No adverse event with COMIRNATY and COMIRNATY..Concurrent medical conditions included Type 2 diabetes mellitus, Hypothyroidism on 01-Jan-1996, Chronic renal insufficiency (stage IV) and Decompensation cardiac (heart disease) on 01-Jan-2021..Concomitant products included LEVOTHYROXINE SODIUM (EUTIROX) for Hypothyroidism, TRAZODONE HYDROCHLORIDE (TRITTICO), FUROSEMIDE (LASIX P), ATORVASTATIN CALCIUM (TORVAST), FLUPHENAZINE DECANOATE (FLUVION), CETIRIZINE, WARFARIN SODIUM (COUMADIN), LANSOPRAZOLE (LANSOX), METOLAZONE (ZAROXOLYN), CALCITRIOL, SERTRALINE HYDROCHLORIDE (ZOLOFT), BISOPROLOL and INSULIN GLARGINE (ABASAGLAR) for an unknown indication.. ..On 15-Nov-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On 16-Jan-2022, the patient experienced SHOCK (acute on chronic renal failure requiring dialysis, shock, anasarcatic congestive state, cardiomegaly) (seriousness criterion death), ACUTE KIDNEY INJURY (acute on chronic renal failure requiring dialysis, shock, anasarcatic congestive state, cardiomegaly) (seriousness criterion death), CARDIOMEGALY (acute on chronic renal failure requiring dialysis, shock, anasarcatic congestive state, cardiomegaly) (seriousness criterion death) and GENERALISED OEDEMA (acute on chronic renal failure requiring dialysis, shock, anasarcatic congestive state, cardiomegaly) (seriousness criterion death). The patient died on 28-Jan-2022. The reported cause of death was Shock cardiogenic. An autopsy was not performed. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 16-Jan-2022, Abdominal X-ray: negative (Negative) Negative..On 16-Jan-2022, Blood gases: negative (Negative) Negative..On 16-Jan-2022, Blood test: negative (Negative) Negative..On 16-Jan-2022, Chest X-ray: negative (Negative) Negative..On 16-Jan-2022, Specialist consultation: negative (Negative) Negative..On 16-Jan-2022, Ultrasound scan: negative (Negative) Negative..On 17-Jan-2022, Echocardiogram: negative (Negative) Negative..On 17-Jan-2022, SARS-CoV-2 test: negative (Negative) Negative.. . .The action taken with mRNA-1273

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		(Spikevax) (Intramuscular) was unknown.. .For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.. .It was reported that on 28-Jan-2022, the patient died from irreversible cardiogenic shock. .Treatment mediations were not reported...Senders comment: Clinical report provided by the reporter was attached. On 28 Jan 2022 the patient died of irreversible cardiogenic shock...Company comment: This regulatory authority case concerns a 77-year-old female patient, with relevant medical history of stroke in 2017 and concurrent conditions type 2 diabetes mellitus, cardiac decompensation and chronic renal insufficiency, who experienced the serious, unexpected fatal events of shock, generalized edema, cardiomegaly and acute kidney injury (AESI). The events occurred approximately 2 months after the 3rd dose of mRNA 1273. Additionally, there was an interchange of vaccine products as the patient was previously vaccinated with 2 doses of Comirnaty. The patient passed away12 days after the onset due to irreversible cardiogenic shock. It is unknown whether autopsy was performed. The patient's advanced age, history of stroke and multiple comorbidities (type 2 diabetes mellitus, heart disease and chronic renal insufficiency) remain confounders for the events and the fatal outcome. Additionally, concomitant furosemide is a possible confounder for shock and AKI, fluphenazine for AKI and metolazone for renal insufficiency. The benefit-risk relationship of mRNA 1273 vaccine is not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 07-Mar-2022: Follow-up Received : Lab test result (Abdominal X-ray NOS, Arterial blood gases, Blood test NOS, CXR, Echocardiography, COVID-19 PCR test, Nephrologist consultation, Echography) updated.
[redacted]		This regulatory authority case was reported by an other health care professional and describes the occurrence of CARDIAC ARREST (Cardiac arrest, OHCA, and suspect cardiogenic or adverse reaction caused by unspecific reasons) and ADVERSE DRUG REACTION (Cardiac arrest, OHCA, and suspect cardiogenic or adverse reaction caused by unspecific reasons) in a 60-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 050F21A) for COVID-19 vaccination. . .Previously administered products included for Product used for unknown indication: COVID-19 vaccine: AZ vaccines (The first two doses of COVID-19 vaccine: AZ vaccines, felt unwell (fever, hand swelling, drowsiness, nausea and vomiting and etc.) after injection)..Past adverse reactions to the above products included Feeling unwell with COVID-19 vaccine: AZ vaccines.. ..On 14-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) .25 milliliter. On 16-Jan-2022, the patient experienced CARDIAC ARREST (Cardiac arrest, OHCA, and suspect cardiogenic or adverse reaction caused by unspecific reasons) (seriousness criterion death) and ADVERSE DRUG REACTION (Cardiac arrest, OHCA, and suspect cardiogenic or adverse reaction caused by unspecific reasons) (seriousness criterion death). It is unknown if an autopsy was performed. . . .For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments...The patient had no history of chronic diseases or long-term medication (according to family members)...On 14 Jan 2022, because the patient worked at a betel nut stall, the patient's daughter worried that her mother may be infected. On the morning, she assisted her mother to make an appointment for additional vaccination. ..On 14 Jan 2022, the patient received Moderna COVID-19 additional vaccine. On 14 Jan 2022 evening, after vaccination, the patient's daughter called to inquire about the patient's condition, and the patient responded without any discomfort. ..On 16 Jan 2022, at 5:22, the patient was sent to the emergency room by EMT ambulance, and the breathing and heartbeat could not be detected. The patient had difficulty breathing at night, and the patient's neighbor called 119 at 4:46. When EMT arrived at the scene, the patient had OHCA, and the patient's neighbor denied that the patient had been unwell before that. The patient was not traumatized...Investigations were reported as Cons: E1V1M1 Conj: (Normal) Sclera: (Normal) Pupil: (Dilated) Left:4 mm Right:4 mm Light reflex (-) Light reflex(-) Neck: (Supple) Jugular vein: (Flat) Chest: (Symmetric) No breathing No Heart sound Extremities: (Flaccid)(Cold). ..On 16 Jan 2022, doctor explained the situation to the family members, and gave the patient emergency drugs, intubation, extracardiac massage, and ambubagging keep air way CPR from 5:22 - 6:07. Echo showed heart nearly no movement, EKG showed PEA Pupil dilated without light reflex. Patient expired on 06:07 am 16 Jan 2022.Emergency medicine was Adrenalin 1mg/ml/amp 1amp ST IVP with total dose of 10amp Injection of sodium bicarbonate 8amp ST IVP with total dose of 8 amp...On 16 Jan 2022, the family told us that the patient received Moderna vaccine (additional vaccine) on 14-Jan. As the patient had no chronic diseases or long-term medication, and had discomfort with the previous AZ vaccine, the family suspected that the patient's condition was related to the adverse reaction of the vaccine and the cold weather...After the first dose of AZ vaccine the patient felt very unwell, the daughter helped to take care of her, and the patient had a fever, swollen hands, drowsiness, nausea, etc. (Health Center informed that the patient was hospitalized due to discomfort after the first dose of vaccine, but the accuracy of the information remains to be verified). The second dose of AZ vaccine, patient felt unwell, but the symptoms were milder than that of the first dose, with slight fever.After the third dose, patient didn't report discomfort

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		on the night after the injection and didn't reported dyspnea until the morning of 16 Jan 2022...On 16 Jan 2022, the patient's data on inspection and examination in emergency room was creatinine 1.4mg/dL, ALT 85U/L K+ 6.3mMol/L, Glucose-Random 467mg/dL(relatively high), SARS-CoV-2 PCR Negative, CK-MBmass 1.93ng/mL, cardiac Troponin T 79ng/L, Hct 45.5%, MCV 103.4fL, MCHC 28.8g/dL PLT 56x1000/uL, WBC 12.50x1000/uL...On 16 Jan 2022, Health Center informed the police that the patient called the proprietress of the betel nut stall that morning, told her that she was unwell. The shop could not be opened that morning, and then the patient fainted and fell, and the proprietress assisted her in sending her to the hospital. (The correctness of the data remains to be verified)...The first dose of AZ took on 17-Jul-2021, the second dose of AZ on 08-Oct-2021. The boss called 119 urgently and helped to send her for emergency treatment on 16-Jan-2022 due to dyspnea and physical discomfort. At 6:07, she was declared dead after the emergency treatment was invalid. On 17 Jan 2022, Hospital reported the case, Health Bureau also replied that it had contacted the family members (the patient's daughter) to apply for VICP. The patient's daughter said that the Chiayi District Prosecutor's Office changed the arrangement of autopsy to 8:30 a.m of 18 Jan 2022 and Chiayi County Health Bureau also assisted in applying for VICP. Judicial anatomy was conducted on 19 Jan 2022. On 26 Jan 2022, anatomical results of 18 Jan 2022 were intestinal vein embolism with posterior abdominal hemorrhage and Pulmonary embolism... .Company Comment - This regulatory authority case concerns a 60 year old female patient with no relevant medical history, who experienced the serious unexpected events of cardiac arrest and adverse reaction. The events occurred 2 days after the third dose of mRNA-1273 vaccine. The outcome of the events were fatal, with death occurring on the same day. The rechallenge was not applicable as there are no plans for future dosing. The benefit-risk relationship of the mRNA-1273 vaccine is not. .Most recent FOLLOW-UP information incorporated above includes:.On 25-Apr-2022: Follow-up document received contains non significant information (event verbatim were updated).
[redacted]		This regulatory authority case was reported by an other health care professional and describes the occurrence of SYNCOPE (Faint) in a 61-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 072F21A_1110129-CDC) for COVID-19 vaccination. . .The patient's past medical history included Renal dialysis..Previously administered products included for Product used for unknown indication: ASTRAZENECA COVID-19 VACCINE (first dose) on 17-Jun-2021 and ASTRAZENECA COVID-19 VACCINE (second dose) on 23-Sep-2021..Past adverse reactions to the above products included No adverse event with ASTRAZENECA COVID-19 VACCINE and ASTRAZENECA COVID-19 VACCINE..Concurrent medical conditions included Diabetes and Hypertension.. ..On 18-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 20-Jan-2022, the patient experienced SYNCOPE (Faint) (seriousness criterion death). The patient died on 20-Jan-2022. The reported cause of death was Faint. An autopsy was performed. The autopsy-determined cause of death was Atherosclerotic cardiovascular disease and end-stage renal disease. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On an unknown date, SARS-CoV-2 test: result pending Result pending.. . .For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.. .WWID was reported as [redacted] .No concomitant medication was provided..On 19-Jan-2022, the patient said to her neighbor that she had symptoms of discomfort such as limb weakness, vomiting and diarrhea. On 20-Jan-2022, her neighbor found that she had not gone out, then her neighbor entered her room to visit the patient with the key given by the deceased. The neighbor found that the patient fell down on the ground, then the neighbor dialed phone. When the relevant personnel arrived at the site and assessed that the patient had died obviously, the patient was not sent to the hospital. Preliminary study and judgment report of forensic anatomy on 24-Jan-2022, showed atherosclerotic cardiovascular disease (90percentage of the three major coronary arteries were blocked), and end-stage renal disease (renal dialysis). Judicial autopsy was performed on 24-Jan-2022..No treatment medication was provided...Company comment:.This regulatory authority follow up case concerns a 61 year old female patient with relevant medical history of renal dialysis, diabetes and hypertension, who met with the unexpected fatal (seriousness criterion-death) event of Syncope, about 2 days after receiving the third dose with mRNA-1273 vaccine in the COVID-19 vaccination series. The event had a fatal outcome with death occurring on the 3rd day of vaccine administration. Patient reported of symptoms of discomfort such as limb weakness, vomiting and diarrhea on the second day of vaccination. On the third day, she fell down on the ground and was found by her neighbor. The rescue team was called but could not revive her. The patient received the previous two doses with AstraZeneca Covid-19 vaccine with no reported adverse events, the last dose being given about 3 months and 26 days prior to mRNA-1273 vaccine. Interchange of vaccine products was noted. The autopsy report revealed the cause of death as Syncope along with Atherosclerotic cardiovascular disease and End stage renal disease. Medical history of renal dialysis, diabetes and hypertension could be confounding for the

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		event Syncope. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event's seriousness retained as per Regulatory Authority reporting..... .Most recent FOLLOW-UP information incorporated above includes:.On 25-Apr-2022: Significant follow-up appended, Patient id, history, cause of death, autopsy result, lab test, event verbatim, and I-narrative updated.
[redacted]		This regulatory authority case was reported by an other health care professional and describes the occurrence of SYNCOPE (Faint) in a 63-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 050F21A_1110124-CDC) for COVID-19 vaccination. . .The patient's past medical history included Haemodialysis..Previously administered products included for COVID-19 vaccination: AZ vaccine (vaccinated in Antai Hospital) on 17-Jun-2021 and AZ vaccine (vaccinated in Antai Hospital) on 23-Sep-2021..Past adverse reactions to the above products included No adverse event with AZ vaccine and AZ vaccine..Concurrent medical conditions included End stage renal disease (ESRD), Type 2 diabetes mellitus, Hypertension and Hepatitis B carrier.. ..On 13-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) .25 milliliter. On 14-Jan-2022, the patient experienced SYNCOPE (Faint) (seriousness criterion death). The patient was treated with NORMAL SALINE (intravenous) at a dose of 500 ml IV ST; NAHCO3 (intravenous) at a dose of 1 dosage form, 6 Amp IV ST; EPINEPHRINE (intravenous) at a dose of 1 dosage form, 1 amp IV every 3 minutes and EPINEPHRINE (intravenous) on 15-Jan-2022 at a dose of 1 dosage form, 10 Amp. It is unknown if an autopsy was performed. Not Provided . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 15-Jan-2022, SARS-CoV-2 test: negative (Negative) Negative.. . .For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.. .No concomitant medications were provided by the reporter..It was reported that the family member of the patient said that the patient had a poor appetite and general discomfort that day. After returning home in the evening, it was found that the patient fell down on the ground in the room and was unconscious. Phone number 119 was urgently called, and CPCR was performed. EMT personnel checked after arriving and found that the patient had no spontaneous pulse or breathing. After the emergency doctor diagnosed, CPCR was given continuously, an endotracheal tube respirator was placed. By 01/15 00:29, a total number of 10amp epinephrine was given, but the patient still had no spontaneous pulse. After the doctor explained the condition, the family members accepted it, declared the first aid invalid, and sent the patient home by ambulance at 01:40..The follow-up care is as follows.01/18/2022 01/18 Summary of epidemic situation survey of death cases after receiving COVID-19 vaccine in Xinyuan Township, Pingtung County. 01/13 The patient.experienced general malaise, poor appetite, and was found lying unconscious at home in the evening. At 23:56, the family dialed 119 and sent her to Antai Community Hospital. The doctor continued to give CPCR, and put in endotracheal tube respirator, N/S 500ml IV ST, NaHCO3 6amp ST IV and epinephrine 1 amp IV every 3 minutes and it was declared that the first aid was ineffective. On 15-JAN-2022, Antai Hospital reported the adverse vaccine event, and the family member of the patient was followed up for the intention for judicial examination.. .CC: This is a fatal case with interchange of vaccine product reported by the regulatory authority concerning a 63-year-old, female patient with medical history of hepatitis B, hypertension, type 2 diabetes and, end stage renal disease, who experienced the unexpected fatal event of syncope. One day after the administration of the booster dose of mRNA-1273 vaccine, the patient experienced general malaise, poor appetite, and was found lying unconscious at home. Patient was treated with cardiopulmonary resuscitation, IV epinephrine and fluids, unsuccessfully. Underlying conditions are confounders. Patient has had received 2 doses of COVID-19 Vaccine from another pharmaceutical company (AstraZeneca) approximately 4 months prior to mRNA-1273 vaccine. Cause of death was no further specified. It is unknown if autopsy was performed. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report..Most recent FOLLOW-UP information incorporated above includes:.On 25-Apr-2022: Non significant follow up received.
[redacted]		This spontaneous case was reported by a physician and describes the occurrence of ACUTE MYOCARDIAL INFARCTION (Painless acute myocardial infarction) and CARDIO-RESPIRATORY ARREST (Cardio-respiratory arrest) in an 86-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (batch no. 3005786) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. . .The patient's past medical history included Femoral neck fracture (Left femoral neck fracture) and Lumbar spine compression fracture (Lumbar vertebral compression fracture L4) on 12-Nov-2019..Previously administered products included for Product used for unknown indication: Comirnaty on 18-May-2021 and Comirnaty on 14-Jun-2021..Past adverse reactions to the above products included No adverse event with Comirnaty and Comirnaty..Concurrent medical conditions included Hypertension, Diabetes mellitus, Chronic eczema, Dementia, Insomnia, Late effects of cerebral infarction, Cardiac failure chronic and Low back pain..Concomitant products included ESOMEPRAZOLE

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		MAGNESIUM (NEXIUM EBB), RUPATADINE FUMARATE (RUPAFIN), MEMANTINE HYDROCHLORIDE (MEMANTINE HYDROCHLORIDE OD), SERTRALINE, ACETYLSALICYLIC ACID (BAYASPIRIN), ZOLPIDEM TARTRATE, CELECOXIB and AMLODIPINE for an unknown indication.. ..On 07-Feb-2022, the patient received third dose of mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (Intramuscular) .25 milliliter. On 08-Feb-2022, the patient experienced ACUTE MYOCARDIAL INFARCTION (Painless acute myocardial infarction) (seriousness criteria death and medically significant), CARDIO-RESPIRATORY ARREST (Cardio-respiratory arrest) (seriousness criteria death and medically significant), FEELING ABNORMAL (Strange feeling) and MALAISE (Malaise in the body). The patient died on 08-Feb-2022. The reported cause of death was painless acute myocardial infarction and Cardio-respiratory arrest. An autopsy was not performed. At the time of death, FEELING ABNORMAL (Strange feeling) and MALAISE (Malaise in the body) outcome was unknown. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 28-Jun-2021, Alanine aminotransferase (10-42): 11 (normal) 11 international unit per litre..On 28-Jun-2021, Aspartate aminotransferase (13-30): 17 (normal) 17 international unit per litre..On 28-Jun-2021, Blood bilirubin (0.4-1.5): 0.5 (normal) 0.5 milligram per decilitre..On 28-Jun-2021, Blood calcium (8.8-10.1): 8.9 (normal) 8.9 milligram per decilitre..On 28-Jun-2021, Blood cholesterol (142-248): 209 (normal) 209 milligram per decilitre..On 28-Jun-2021, Blood creatinine (0.65-1.07): 1.18 (High) 1.18 milligram per decilitre..On 28-Jun-2021, Blood glucose (73-109): 103 (normal) 103 milligram per decilitre..On 28-Jun-2021, Blood lactate dehydrogenase (124-222): 162 (normal) 162 international unit per litre..On 28-Jun-2021, Blood potassium (3.6-4.8): 4.0 (normal) 4.0 millimole per litre..On 28-Jun-2021, Blood sodium (138-145): 143 (normal) 143 millimole per litre..On 28-Jun-2021, Blood triglycerides (40-149): 157 (High) 157 milligram per decilitre..On 28-Jun-2021, Blood urea (8-20): 24 (High) 24 milligram per decilitre..On 28-Jun-2021, Blood uric acid (3.7-7.8): 8.3 (High) 8.3 milligram per decilitre..On 28-Jun-2021, Eosinophil count (Unknown-6.0): 7.6 (High) 7.6 % percent..On 28-Jun-2021, Gamma-glutamyltransferase (13-64): 25 (normal) 25 international unit per litre..On 28-Jun-2021, Glycosylated haemoglobin (4.9-6.0): 6.6 (High) 6.6 % percent..On 28-Jun-2021, High density lipoprotein (40-90): 33 (normal) 33 milligram per decilitre..On 28-Jun-2021, LDL/HDL ratio: 5.3 5.3..On 28-Jun-2021, Low density lipoprotein (65-139): 152 (High) 152 milligram per decilitre..On 28-Jun-2021, Mean cell haemoglobin concentration (31.7-35.3): 31.5 (normal) 31.5 gram per decilitre..On 28-Jun-2021, N-terminal prohormone brain natriuretic peptide (Unknown-125): 164 (High) 164 picogram per millilitre..On 28-Jun-2021, White blood cell count: 7800 7800..On 07-Feb-2022, Blood pressure measurement: 120/82 120/82..On 07-Feb-2022, Body temperature: 36.2 36.2 degree Celsius..On 07-Feb-2022, Heart rate: 96 96..On 08-Feb-2022, Breath sounds: no sound was heard No sound was heard..On 08-Feb-2022, Carotid pulse: no pulse was felt No pulse was felt..On 08-Feb-2022, Heart sounds: no sound was heard No sound was heard..On 08-Feb-2022, Pupillary light reflex tests: disappeared Disappeared..On an unknown date, Body temperature: 36.2 36.2 degree Celsius.. . .For mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (Intramuscular), the reporter considered ACUTE MYOCARDIAL INFARCTION (Painless acute myocardial infarction), CARDIO-RESPIRATORY ARREST (Cardio-respiratory arrest), FEELING ABNORMAL (Strange feeling) and MALAISE (Malaise in the body) to be possibly related. . .Company comment:.This case concerns a 86-year-old male patient with hypertension and diabetes mellitus, who experienced the fatal serious unexpected events of acute myocardial infarction and cardio-respiratory arrest, on the next following day after receiving the third dose of mRNA-1273. It was reported patient appeared to be in good physical condition the night he received the vaccine. The patient experienced malaise in the body and strange feeling. The patient was found seated on the toilet in a state of cardio-respiratory arrest. Pupillary reflex disappeared, no heart sounds or breathing sounds were heard, and no pulse was felt in the carotid artery. Cause of death was reported as painless acute myocardial infarction. Advanced age and patient's medical history remains as confounders. The benefit-risk relationship of mRNA-1273 is not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 22-Feb-2022: Follow up document received and contains Patient demographic information added, laboratory data added, concomitant product added and event added.
[redacted]		This regulatory authority case was reported by an other health care professional and describes the occurrence of HEADACHE (Headache), VOMITING (Vomiting) and SYNCOPE (Faint) in a 72-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. . .The patient's past medical history included Renal dialysis (Had been receiving renal dialysis in Clinic for 9 years)..Previously administered products included for Product used for unknown indication: Astrazeneca and Astrazeneca..Past adverse reactions to the above products included Fever with Astrazeneca and Astrazeneca..Concurrent medical conditions included Diabetes mellitus (DM).. ..On 19-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-

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		19 Vaccine) (Intramuscular) 1 dosage form. On 28-Jan-2022, the patient experienced HEADACHE (Headache) (seriousness criterion death), VOMITING (Vomiting) (seriousness criterion death) and SYNCOPE (Faint) (seriousness criterion death). The reported cause of death was Headache, Vomiting and Faint. It is unknown if an autopsy was performed. . . .For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.. .The patient with OHCA was admitted to the emergency department..Company Comment: This regulatory authority case concerns a 72-year-old female patient, with relevant medical history of Diabetes Mellitus and has been receiving hemodialysis procedure for nine years, who experienced the unexpected serious fatal events of Headache, Vomiting and Syncope, which occurred 9 days after receiving a dose mRNA-1273 vaccine taken as third dose of COVID-19 immunization. Interchange of vaccine products is noted in this case as patient received 2 doses of AstraZeneca COVID-19 vaccine on unspecified dates prior to mRNA-1273 administration. The events were accompanied by loss of consciousness which prompted the pre-hospital emergency response. She was noted to have no vital signs prior admission in the emergency room. Death occurred approximately 9 days after receiving the third dose of mRNA-1273 vaccine. The cause of death was reported as Headache, Vomiting and Syncope. It is unknown if an autopsy was performed. Advanced age and medical history remain as confounders for the events and for the fatal outcome. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per regulatory authority's report.. .Most recent FOLLOW-UP information incorporated above includes:.On 25-Apr-2022: Follow-up document received: Medical history was updated, LLT of event syncope was changed to faint and cause of death was added.
[redacted]		This case was initially received via an unknown source (no reference has been entered for a health authority or license partner) on 07-Feb-2022. The most recent information was received on 25-Apr-2022 and was forwarded to Moderna on 25-Apr-2022. .This regulatory authority case was reported by an other health care professional and describes the occurrence of ASTHMA (Respiratory asthma) and CHEST DISCOMFORT (chest tightness) in a 72-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. . .The patient's past medical history included Graft failure (SVG failure), Stent placement (cardiac catheter stent was implanted), CABG (s/p CABG with SVG failure), Bare metal coronary stent placement (s/p DES to proximal and mid LAD and BMS to distal LAD, with ISR in DES in p- and m-LADs/p DEB and BMS, s/p BMS to distal LAD.), Drug-eluting stent placement (s/p DES to proximal) and Dialysis since an unknown date..Previously administered products included for Product used for unknown indication: Aztrazenica..Past adverse reactions to the above products included Chest tightness with Aztrazenica..Concurrent medical conditions included Coronary artery disease (CAD, 3VD) since January 2020, Mitral regurgitation (Moderate) and End stage renal disease (ESRD) (on HD135).. ..On 10-Jan-2022, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 11-Jan-2022, the patient experienced ASTHMA (Respiratory asthma) (seriousness criterion death) and CHEST DISCOMFORT (chest tightness) (seriousness criterion death). The patient was treated with NITROGLYCERIN at an unspecified dose and frequency. The reported cause of death was respiratory asthma, Chest tightness, Heart failure and Kidney failure. It is unknown if an autopsy was performed. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 11-Jan-2022, Blood pressure measurement: 91/60 (Low) 91/60 mmHg and 119/76 119/76 mmHg..On 11-Jan-2022, Body temperature: 36.2 36.2°C;..On 11-Jan-2022, Coma scale: e2v1m3 E2V1M3..On 11-Jan-2022, Electrocardiogram: standstill standstill..On 11-Jan-2022, Heart rate: 86 86 BPM..On 11-Jan-2022, Oxygen saturation: 82 82%, and after O2 mask was used, 88 88%, 92 92% and 82 82%..On 11-Jan-2022, Respiratory rate: 36-38 36-38 times/min and 32 32 times/min..On 11-Jan-2022, Vital signs measurement: had no vital signs had no vital signs.. . .For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.. .No concomitant medications were reported..Company comment: This fatal regulatory authority case concerns a 72-year-old male patient, with medical history of graft failure (reported as SVG failure), coronary artery bypass, bare metal coronary stent placement, coronary artery disease, mitral regurgitation and drug-eluting stent placement, who experienced the serious (due to death) unexpected events of ASTHMA and CHEST DISCOMFORT, on the following day he received a dose of mRNA-1273 vaccine, considered as the second dose of the vaccination schedule, and died on the same day that the events occurred. he previously received, on an unknown date, a dose of AstraZeneca'S COVID-19 vaccine. According to the narrative of the source document, on the following day of the vaccination with mRNA-1273, his USUAL? renal dialysis, due to his end stage renal disease, HAD TO be suspended because of chest discomfort, dyspnea, desaturation and heart rate increased, for what he was sent to the emergency room, where a severe lung edema was found. his electrocardiogram showed standstill and the patient lost his vital signs. The reported cause of death was a natural death due to his heart and kidney failure and the doctor stated

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		that it did not seem to be an acute heart discomfort caused by the vaccination. It is unknown if an autopsy was performed. The history of graft failure, coronary artery bypass, bare metal coronary stent placement, coronary artery disease, mitral regurgitation and drug-eluting stent placement remain as confounders for chest discomfort. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 25-Apr-2022: Follow-up document contains added cause of death, medical history, lab data, treatment medication, deleted an event (shortness of breath), added new event (respiratory asthma) and updated I-narrative.
[redacted]		This regulatory authority case was reported by an other health care professional and describes the occurrence of PYREXIA (Fever) and DECREASED APPETITE (Loss of appetite) in an 86-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 072F21A_1110129-CDC) for COVID-19 vaccination. . .Previously administered products included for Product used for unknown indication: Astrazeneca (1st dose) on 15-Jun-2021 and Astrazeneca (2nd dose) on 18-Sep-2021..Past adverse reactions to the above products included No adverse effect with Astrazeneca and Astrazeneca..Concurrent medical conditions included Bronchiectasis (Suffered from bronchiectasis for many years.and received treatment.).. ..On 20-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) .25 milliliter. On 25-Jan-2022, the patient experienced PYREXIA (Fever) (seriousness criterion death) and DECREASED APPETITE (Loss of appetite) (seriousness criterion death). The patient was treated with PARACETAMOL (PANADOL) at an unspecified dose and frequency. It is unknown if an autopsy was performed. . . .For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.. .Concomitant medication was not provided..Patient's family member complained that after the first two doses of AZ there was no special discomfort and reaction, but recently the patient was weak and had a poor appetite. The patient was ill the next day after returning home. Patient took Panadol but her body was still weak. Till January 25, the patient was sleepy and could not be woken up and later died, without being sent to see a doctor..On Jan'28-2022 The daughter of the patient explained that her mother had passed away and she will consider whether to apply for VICP after the Spring Festival..Treatment information was not reported...Company comment: This is a regulatory case concerning an 86 year-old, female patient with a history of Bronchiectasis and Interchange of vaccine products (vaccination with two doses of COVID-19 vaccine AstraZeneca approximately 3 months prior), who experienced the serious Fatal unexpected, events of pyrexia and Decreased appetite, approximately 5 days after the booster dose of mRNA-1273 vaccine. It was reported she felt unwell, weak, sleepy and was found dead 5 days after the vaccination, cause of death was not further specified and there was no hospital visit. It is unknown whether an autopsy was performed. The mentioned medical history and patient´s advanced age remain as confounders for the fatal outcome. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 25-Apr-2022: Follow up received and had no new information.
[redacted]		This case was initially received via European Medicines Agency (Reference number: [redacted] on 08-Feb-2022. The most recent information was received on 16-Feb-2022 and was forwarded to Moderna on 16-Feb-2022. .This regulatory authority case was reported by a consumer and describes the occurrence of CARDIAC ARREST (Cardiac arrest died within 24 hours of vaccination) in an 82-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. . .The patient's past medical history included Venous thromboembolism, Gastroesophageal reflux disease, Post herpetic neuralgia (chronic nerve pain due to shingles.), Renal function disorder and Syncope on 27-Nov-2021..Previously administered products included for Product used for unknown indication: COVID-19 vaccine Pfizer COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST (COVID-19 vaccine Pfizer COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST) in February 2021, COVID-19 vaccin Pfizer COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST (COVID-19 vaccin Pfizer COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST) in April 2021 and griepprik INFLUENZAVACCIN (NIET GESPECIFICEERD) (griepprik INFLUENZAVACCIN (NIET GESPECIFICEERD)) on 11-Nov-2021..Past adverse reactions to the above products included Flu-like illness with COVID-19 vaccin Pfizer COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST; Flu-like symptoms with COVID-19 vaccine Pfizer COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST; and No adverse event with griepprik INFLUENZAVACCIN (NIET GESPECIFICEERD)..Concurrent medical conditions included Short stature (original length 1.60 m, severe osteoporosis made very shrunk. Intestines and lungs were oppressed .), Epilepsy since 1993, Hypertension (doubt if she had high blood pressure. I think so and that was brought down with

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		medication.) and Osteoporosis..Concomitant products included CALCIUM CARBIMIDE (CALCIUMCARBIMIDUM), FENTANYL (FENTANYL CT), IPRATROPIUM BROMIDE (IPRATROPIUM BR), LIDOCAINE HYDROCHLORIDE (LIDOCAINE NMD), SIMVASTATINE, DENOSUMAB, GABAPENTINE and LEVETIRACETAM (LEVETIRACETAM TEVA) for an unknown indication.. ..On 12-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 12-Dec-2021, the patient experienced MALAISE (immediately after vaccination, chillful and general malaise) and CHILLS (immediately after vaccination, chillful and general malaise). On 13-Dec-2021, the patient experienced CARDIAC ARREST (Cardiac arrest died within 24 hours of vaccination) (seriousness criterion death). The patient died on 13-Dec-2021. The reported cause of death was cardiac arrest after booster vaccination. An autopsy was not performed. At the time of death, MALAISE (immediately after vaccination, chillful and general malaise) and CHILLS (immediately after vaccination, chillful and general malaise) outcome was unknown. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.In November 2021, Specialist consultation: she collapsed during shopping a week or 3 before t She collapsed during shopping a week or 3 before the booster, and no cause has been found. There was consultations with the neurologist about epilepsy at the time, but it was not related to that... . . . .Treatment information was not provided...Company comment:.This is a regulatory authority case concerning a 82-year-old, female patient with relevant medical history of venous thromboembolism, hypertension and syncope, relevant concurrent medical conditions of osteoporosis with intestinal and lung compression, epilepsy and renal function disorder and relevant concomitant use of fentanyl, who experienced the unexpected serious event of cardiac arrest, the unexpected non-serious event of general malaise and expected non-serious event of chills. The events general malaise and chills occurred 1 hour after the unknown dose number of mRNA-1273 vaccine administration while the event cardiac arrest occurred 22 hours after the unknown dose number of mRNA-1273 vaccine administration. The event cardiac arrest resulted to death. The reported cause of death is cardiac arrest. Autopsy was not performed. The medical history of venous thromboembolism, hypertension, syncope, concurrent medical conditions of osteoporosis with intestinal and lung compression, epilepsy, renal function disorder and the concomitant use of fentanyl remain confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 16-Feb-2022: Follow up received on 16-Feb-2022 and contains updated relevant medical history and concomitant medication added.
[redacted]	[redacted]	This case was received via European Medicines Agency (Reference number: [redacted]) on 09-Feb-2022 and was forwarded to Moderna on 09-Feb-2022. .This regulatory authority case was reported by a physician and describes the occurrence of DEATH (found dead by the husband in the morning (23.01.22).) in a 78-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 216045) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. . .The patient's past medical history included Tachyarrhythmia absoluta, Tetraplegia, Lung fibrosis, COVID-19 in February 2021, Leg venous thrombosis in 2017 and Myopathy..Previously administered products included for Prophylactic vaccination: Comirnaty BNT162b2 on 30-Jul-2021..Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2.. ..On 22-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 3 dosage form. On 22-Jan-2022, the patient experienced INFLUENZA LIKE ILLNESS (Strong freezing, nausea and vomiting, after a few hours of improvement, went to bed). The patient died on an unknown date. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, INFLUENZA LIKE ILLNESS (Strong freezing, nausea and vomiting, after a few hours of improvement, went to bed) had not resolved. . . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .Concomitant medications details were not reported by the reporter..Treatment details was not reported by the reporter...Company comment: This case concerns a 78-year-old female patient with medical history of Tachyarrhythmia absoluta, Tetraplegia, Lung fibrosis, COVID-19 in February 2021, Leg venous thrombosis in 2017 and Myopathy, who died on unknown date after administration of mRNA-1273. The cause of death was not reported. It is unknown if an autopsy was performed. It was also reported that the patient experienced non-serious INFLUENZA LIKE ILLNESS on the same day after vaccine administration. The patient's medical history of Tachyarrhythmia absoluta, Tetraplegia, Lung fibrosis and Leg venous thrombosis remain strongly confounding. The reporter did not provide causality assessment. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Having in mind that this patient received the COVID-19 VACCINE PFIZER prior to vaccination with the company product, Interchange of vaccine products should have been considered in this specific case.
[redacted]	[redacted]	This case was initially received via European Medicines Agency (Reference number: [redacted] on 09-Feb-2022. The most recent information was received on 21-Mar-2022 and was forwarded to Moderna on 21-Mar-2022. .This regulatory authority case was reported by a physician

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		and describes the occurrence of CIRCULATORY COLLAPSE (Person collapsed 10 minutes after vaccination), DYSPNOEA (CPR setting, < 2 minutes after vaccine pale and gasping, CPR started), MYOCARDIAL INFARCTION (At autopsy, there was a pinpoint lumen and a huge plug in the coronary artery just after the deflection downwards (forgot the 3 letters of the abbreviation for a moment). In short: he is unmistakable died of a heart attack) and PALLOR (CPR setting, < 2 minutes after vaccine pale and gasping, CPR started) in a 77-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 094F21A) for COVID-19 vaccination. . .The patient's past medical history included CVA (No Family history)..Previously administered products included for Product used for unknown indication: COMIRNATY on 02-Jun-2021 and COMIRNATY on 07-Jul-2021..Past adverse reactions to the above products included No adverse event with COMIRNATY and COMIRNATY.. ..On 18-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 18-Jan-2022, the patient experienced CIRCULATORY COLLAPSE (Person collapsed 10 minutes after vaccination) (seriousness criterion death) and MYOCARDIAL INFARCTION (At autopsy, there was a pinpoint lumen and a huge plug in the coronary artery just after the deflection downwards (forgot the 3 letters of the abbreviation for a moment). In short: he is unmistakable died of a heart attack) (seriousness criterion death). 18-Jan-2022, the patient experienced DYSPNOEA (CPR setting, < 2 minutes after vaccine pale and gasping, CPR started) (seriousness criterion death) and PALLOR (CPR setting, < 2 minutes after vaccine pale and gasping, CPR started) (seriousness criterion death). The patient died on 18-Jan-2022. The reported cause of death was hartinfarct. An autopsy was performed. The autopsy-determined cause of death was hartinfarct. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On an unknown date, Autopsy: unmistakably died due to myocardial infarction. Obduction revealed a pinpoint lumen and huge gag in the coronaria artery just after the deflection down (forgot the 3 letters of the abbreviation). In short: he has unmistakably died due to myocardial infarction... . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .Concomitant product use was not provided by reporter..Treatment information was not provided...Company comment: This case concerns a 77-year-old male patient with medical history of CVA, who experienced serious due to death, unexpected events of pallor, dyspnea, circulatory collapse and myocardial infarction. The events occurred on the same day after receiving a dose of mRNA-1273 Vaccine. Additionally, there was an interchange of vaccine products as the patient was previously vaccinated with 2 doses of Comirnaty. Reportedly, less than 2 minutes after vaccination, the patient became pale, started gasping and collapsed. Cardiopulmonary resuscitation was initiation however, the patient passed away. The autopsy report showed that the patient passed away from myocardial infarction. The patient's advanced age and history of CVA suggesting unreported cardiovascular disease are possible confounders. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. The events reported and seriousness assessment retained as per regulatory authority reporting.. .Most recent FOLLOW-UP information incorporated above includes:.On 21-Mar-2022: Significant follow-up information received on 21-MAR-2022. Historical condition CVA, Death date, Autopsy result, cause of death added, Laboratory data, New Events cardiovascular collapse and myocardial infarction were added, Event gasping and pale seriousness updated from life threatening to death, Outcome of events gasping and pale updated from unknown to fatal..On 21-Mar-2022: Translation document received on 29-Mar-2022. Reaction/event as reported by primary source were translated, contains non-significant information.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 10-Feb-2022 and was forwarded to Moderna on 10-Feb-2022. .This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (cause of death unknown), CARDIAC DISCOMFORT (pain in the shoulder and thoracic spine, heart anxiety, breathing problems.), MYALGIA (pain in the shoulder and thoracic spine, heart anxiety, breathing problems.) and DYSPNOEA (pain in the shoulder and thoracic spine, heart anxiety, breathing problems.) in a 51-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 042G21A) for COVID-19 vaccination. . .Previously administered products included for Prophylactic vaccination: Comirnaty BNT162b2 on 06-May-2021 and Comirnaty BNT162b2 on 17-Jun-2021..Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Comirnaty BNT162b2.. ..On 14-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 3 dosage form. On an unknown date, the patient experienced CARDIAC DISCOMFORT (pain in the shoulder and thoracic spine, heart anxiety, breathing problems.) (seriousness criterion medically significant), MYALGIA (pain in the shoulder and thoracic spine, heart anxiety, breathing problems.) (seriousness criterion medically significant) and DYSPNOEA (pain in the shoulder and thoracic spine, heart anxiety, breathing problems.) (seriousness criterion medically significant). The patient died on 23-Jan-2022. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, CARDIAC DISCOMFORT (pain in the shoulder and thoracic spine, heart anxiety,

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		breathing problems.), MYALGIA (pain in the shoulder and thoracic spine, heart anxiety, breathing problems.) and DYSPNOEA (pain in the shoulder and thoracic spine, heart anxiety, breathing problems.) had not resolved. . . .The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown.. . . .No concomitant medications were reported..No treatment information was provided...Patient experienced pain in the shoulder that slowly worsened towards the thoracic spine. After boosters heart anxiety, breathing problems during shorter walks. Most no. heart attack ending..Event onset date for Cardiac discomfort, Myalgia and Dyspnoea was reported as 21-Oct-2021...This is a fatal case that concerns a 51-year-old male patient with no relevant medical history, who experienced the unexpected serious events of Cardiac Discomfort, Myalgia, and Dyspnea. The events were medically significant as reported by the regulatory authority. The events occurred 3 months before receiving an unspecified dose of mRNA-1273 Vaccine. Patient died 1 month and 10 days after receiving an unspecified dose of mRNA-1273 Vaccine. The cause of death was not reported. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.
[redacted]		This case was initially received via European Medicines Agency (Reference number: [redacted] on 09-Feb-2022. The most recent information was received on 22-Feb-2022 and was forwarded to Moderna on 22-Feb-2022. .This regulatory authority case was reported by a consumer and describes the occurrence of SUDDEN DEATH (My aunt died suddenly the same day. Established cause of death: 'sudden death') in an 87-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 216041) for COVID-19 vaccination. . .The patient's past medical history included Ulcus cruris (No family history) in 2017, Hearing decreased (No family history) in November 2021, Weight loss (No family history) in December 2020, Subclinical hypothyroidism (No family history) in 2013 and Cataract (No family history) in 2015..Previously administered products included for Product used for unknown indication: HYDROCHLOORTHIAZIDE from 08-Feb-2011 to 02-Jun-2011, HYDROCHLOORTHIAZIDE from 05-Mar-2013 to 17-Oct-2014, METOPROLOL (METOPROLOL TABLET MGA 50MG (SUCCINAAT) from 11-Apr-2013 to 17-Oct-2014, COMIRNATY on 12-Apr-2021 and COMIRNATY on 17-May-2021..Past adverse reactions to the above products included No adverse event with COMIRNATY, COMIRNATY, HYDROCHLOORTHIAZIDE, HYDROCHLOORTHIAZIDE and METOPROLOL..Concurrent medical conditions included Hypertension (no drug therapy, keep an eye on and No family history) in 2011, Parkinsonian gait (Mobility problems, possibly parkinsonism and No family history) in August 2020 and Walking aid user (used walker, but could still climb the stairs and walked above with stool and No family history).. .On 15-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. The patient died on 15-Jan-2022. The reported cause of death was mors subita has been identified by a doctor as a cause of death. mors subita can be caused by cardiac arrhythmias and cardiac arrhythmias may be caused by myocarditis.. An autopsy was not performed. . .Concomitant medications were not provided..Treatment information was not provided...Company comment:.This is a regulatory case concerning a 87-year-old, female patient with medical history of Ulcus cruris, Hypertension, Hearing decreased, Parkinsonian gait, Walking aid user, Weight loss, Subclinical hypothyroidism and Cataract, who experienced the unexpected, Fatal event of Sudden death. The event occurred on 15-Jan-22, same day after the first dose of mRNA-1273. The reported cause of death was mors subita has been identified by a doctor. An autopsy was not performed. Above mentioned patient's medical history and advanced age might have contributed to fatal outcome. Patient had previously received two doses of COVID-19 VACCINE PFIZER (Interchange of vaccine products). The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The case was assessed as Serious as per Regulatory Authority report.. .Most recent FOLLOW-UP information incorporated above includes:.On 09-Feb-2022: Translation received on 15-Feb-2022 included event verbatim and cause of death was updated..On 22-Feb-2022: Follow up information received and included Patient Autopsy detail was updated from Unknown to No and New patient medical history and past drug history was added.
[redacted]		This case was initially received via European Medicines Agency (Reference number: [redacted] on 02-Feb-2022. The most recent information was received on 14-Mar-2022 and was forwarded to Moderna on 14-Mar-2022. .This regulatory authority case was reported by a consumer and describes the occurrence of CARDIO-RESPIRATORY ARREST (Cardiorespiratory arrest /infarction), INFARCTION (Infarction) and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) in a 58-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 216035) for COVID-19 vaccination. . .Co-suspect product included non-company product ENALAPRIL MALEATE, HYDROCHLOROTHIAZIDE (ENALAPRIL/HIDROCLOROTIAZIDA VIR) for Hypertension arterial.. .The patient's past medical history included Tabaquism and Hypertension arterial..Concomitant products included TOZINAMERAN (COMIRNATY) from 13-May-2021 to an unknown date for COVID-19 vaccination.. .On 01-Jan-2018, the patient started

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		ENALAPRIL MALEATE, HYDROCHLOROTHIAZIDE (ENALAPRIL/HIDROCLOROTIAZIDA VIR) (unknown route) 1 dosage form..On 11-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, the patient experienced CARDIO-RESPIRATORY ARREST (Cardiorespiratory arrest /infarction) (seriousness criterion death), INFARCTION (Infarction) (seriousness criterion death) and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) (seriousness criterion death). The patient died on 11-Jan-2022. The reported cause of death was cardiorespiratory arrest. It is unknown if an autopsy was performed. . . . . .No treatment medication details was provided...Company comment: This is a Regulatory Authority case concerning a 58-year-old male patient, with relevant medical history of tabaquism, hypertension arterial and obesity (BMI 34.7), who experienced the unexpected, fatal adverse events of interest Cardio-respiratory arrest and Infarction. COVID-19 immunisation was reported as an additional event described as vaccination with 2 doses of Tozinameran approximately 7 months prior to mRNA-1273 (Interchange of vaccine products). The events onset and date of demise occurred on the same day after receiving the mRNA-1273, given as third dose COVID-19 vaccine. Clinical course leading to demise was not provided in the case. The reported cause of death was cardiorespiratory arrest. It is unknown if an autopsy was performed. The medical history and revaccination with different COVID-19 vaccine remain as confounders. Co-suspect product included non-company product Enalapril maleate. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report.. .Most recent FOLLOW-UP information incorporated above includes:.On 02-Feb-2022: Translation received on 13-Feb-2022 and event verbatim updated..On 14-Mar-2022: Follow up received on 14-MAR-2022. Medical History and event verbatim was updated
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 10-Feb-2022 and was forwarded to Moderna on 10-Feb-2022. .This regulatory authority case was reported by a physician and describes the occurrence of SUDDEN CARDIAC DEATH (Sudden cardiac death) in a 40-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. . .Previously administered products included for COVID-19 vaccination: Comirnaty BNT162b2 on 16-Nov-2021..Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2.. ..On 21-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. The patient died on 22-Jan-2022. The reported cause of death was 10049418. It is unknown if an autopsy was performed. . . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .Concomitant medications were not provided..Treatment information was not provided...This is a fatal case that concerns a 40-year-old male patient with no relevant medical history, who experienced the unexpected serious adverse event of special interest, Sudden Cardiac Death. The event led to the eventual demise of the patient as reported by the regulatory authority. The events occurred in 1 month 2 days after receiving an unspecified dose of mRNA-1273 Vaccine. No clinical or treatment details were given. The reported cause of death was Sudden cardiac death. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 17-Feb-2022: Follow up contains no new information..On 22-Feb-2022: Non-significant follow up appended
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 07-Feb-2022 and was forwarded to Moderna on 07-Feb-2022. .This regulatory authority case was reported by a physician and describes the occurrence of SUDDEN DEATH (Sudden death unexplained) in a 63-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 045G21A) for COVID-19 vaccination. . .The patient's past medical history included Pain disorder associated with psychological factors (Chronic pain disorder with somatic and mental factors) in 2013..Previously administered products included for COVID-19 vaccination: Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant])COVID-19 Vaccine AstraZeneca suspension for injectionCOVID-19 Vaccine AstraZeneca on 22-Apr-2021 and Comirnaty BNT162b2 on 13-Jul-2021..Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant])COVID-19 Vaccine AstraZeneca suspension for injectionCOVID-19 Vaccine AstraZeneca.. ..On 12-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. The patient died on 14-Jan-2022. It is unknown if an autopsy was performed. . . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .No concomitant medication information was reported..No treatment medication information was reported...Company Comment: This regulatory case concerns a 63-year-old, male patient with past drug history of administration of a dose of Vaxzevria (AstraZeneca COVID-19 vaccine) on 22Apr2021 and a dose of Comirnaty (BNT162b2 COVID-19 vaccine) on 13Jul2021, who experienced the unexpected, serious event of sudden death. The event occurred 2 days after administration of the booster dose of the Moderna

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		mRNA-1273 vaccine. The patient expired on 14Jan2022 and the cause of death was unknown. It was unknown if an autopsy was performed. The history of administration of a dose of Vaxzevria (AstraZeneca COVID-19 vaccine) and a dose of Comirnaty (BNT162b2 COVID-19 vaccine) remain as confounders. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report.
[redacted]		This case was initially received via European Medicines Agency (Reference number: [redacted] on 11-Feb-2022. The most recent information was received on 10-Mar-2022 and was forwarded to Moderna on 15-Mar-2022. .This regulatory authority case was reported by a consumer and describes the occurrence of CEREBRAL HAEMORRHAGE (right frontal hemorrhage was seen in the drainage pathway with known hydrocephalus), CEREBRAL INFARCTION (Cerebral infarction), PARTIAL SEIZURES (focal seizures due to increased pressure in the brain), CEREBELLAR HAEMORRHAGE (Hemorrhage from right cerebellar vermis with expansion to fourth ventricle and also blood in the side ventricle on the right) and DEVICE DISLOCATION (On 13-Jan the drain was luxated, followed by frequent consciousness checks) in a 69-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. . .The patient's past medical history included Throat cancer (End date in: 2020, Family history-No.For which radiotherapy, no OK. Treated in University Center), Basal cell carcinoma (Family History: No) in 2004 and Breast carcinoma (treated in perfieer hospital.Family History: No) in 2012..Previously administered products included for Product used for unknown indication: COMIRNATY on 08-May-2021 and COMIRNATY on 12-Jun-2021..Past adverse reactions to the above products included No adverse reaction with COMIRNATY; and Urticaria with COMIRNATY..Concurrent medical conditions included Hypertension (Family history-No) and Smoker (16-20 per day.Family History: No)..Concomitant products included PERINDOPRIL ERBUMINE (PERINDOPRIL GA) and LORAZEPAMUM for an unknown indication.. ..On 05-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 06-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced CEREBRAL INFARCTION (Cerebral infarction) (seriousness criterion hospitalization). On 07-Jan-2022, the patient experienced CEREBELLAR HAEMORRHAGE (Hemorrhage from right cerebellar vermis with expansion to fourth ventricle and also blood in the side ventricle on the right) (seriousness criterion hospitalization). On 13-Jan-2022, the patient experienced CEREBRAL HAEMORRHAGE (right frontal hemorrhage was seen in the drainage pathway with known hydrocephalus) (seriousness criterion death), PARTIAL SEIZURES (focal seizures due to increased pressure in the brain) (seriousness criterion life threatening) and DEVICE DISLOCATION (On 13-Jan the drain was luxated, followed by frequent consciousness checks) (seriousness criterion hospitalization). The patient died on 16-Jan-2022. The reported cause of death was Cerebral hemorrhage. An autopsy was not performed. At the time of death, CEREBRAL INFARCTION (Cerebral infarction), CEREBELLAR HAEMORRHAGE (Hemorrhage from right cerebellar vermis with expansion to fourth ventricle and also blood in the side ventricle on the right) and DEVICE DISLOCATION (On 13-Jan the drain was luxated, followed by frequent consciousness checks) was resolving and PARTIAL SEIZURES (focal seizures due to increased pressure in the brain) outcome was unknown. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 06-Jan-2022, Computerised tomogram head: abnormal (abnormal) Focal stenosis in proximal parietal M2 left without perfusion defects. No significant neck vessels further intracranial. stenosis in the..On 06-Jan-2022, Electrocardiogram: abnormal (abnormal) SR 65/min with one-time PAC with compensatory break, IMHA, long QtC time, further normal conductivity times, no ST deviation..On 06-Jan-2022, Laboratory test: abnormal (abnormal) Glucose 5.8 mmol/1; PT INR 1 .12 INR; Hemoglobin 7.6 Platelet 204 x10 9/1; Leucocytes 7.4 x10 9/1; 7.6 mmol/1; Sodium +125 mmol (low!!!) /l; Potassium 3.5 mmol/1; (MDRD) 144 ml/min; EGFR (CKD-EPI) 104 Kreatinine 38 mol/1; Clearance ml/min/1.73 m2; Urea 3.6 mmol/1..On 06-Jan-2022, Physical examination: abnormal (abnormal) A/free B/VAG bdz slightly expiratory humming, which 98% without oxygen. C RR/210/100P 80/min sinus rhythm. Clear awareness, makes good contact. Language: naming 0/5, simple understanding disturbed, executes simple assignment once, not otherwise. HZ: isocore pupils, absent threat reflex right, symmetrical face, M: Barre does not try bdz, symmetrical spontaneous motor skills, squeezes bdz reasonable force. VZR: mutually plantar. Hall/stand: independent undisturbed..On 07-Jan-2022, Computerised tomogram head: abnormal (abnormal) Hemorrhage from cerebellum/vermis re involving expansion to fourth ventricle and also blood in the side ventricle right. hydrocephalus. Tzt MRI Consider (Yet) None..On 09-Jan-2022, Laboratory test: abnormal (abnormal) Hb 8.4 Sodium: 138 mmol/1 Potassium: 2.9 mmol/l Kreatinine: 36 umol/1 MDRD:153 ml/min..On 13-Jan-2022, Computerised tomogram head: abnormal (abnormal) New severe bleeding in the drain-trajectory right frontal, hydrocephalus and previous cerebellar hemorrhage are globally consistent..On 14-Jan-2022, Chest X-ray: abnormal (abnormal) Gastric tube in the stomach. Low rotated recording. good limitation. Bright sinus pleural. Heart, Diaphragm

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		Domes are hili and mediastinum show no abnormalities. Normal pulmonary vessel drawing. There are no abnormalities in both lung fields. No indications for infiltrate or congestive heart failure and abnormal (abnormal) Gastric tube in the stomach. Low rotated recording. good limitation. Bright sinus pleural. Heart, Diaphragm Domes are hili and mediastinum show no abnormalities. Normal pulmonary vessel drawing. There are no abnormalities in both lung fields. No indications for infiltrate or congestive heart failure.. . . . .No treatment information was provided..The husband and daughter thought that perindopril is not the particular antihypertensive drug that patient uses (perindopril was known at the pharmacy). Daughter watches this at home..Company comment.This regulatory authority case concerns a 69-year-old, female patient with medical history of Throat cancer, basal cell carcinoma, breast cancer, smoking and hypertension, who experienced the unexpected AESI fatal event of Cerebral haemorrhage, unexpected life-threatening event of Partial seizures and unexpected serious (hospitalization) events of Cerebral infarction (AESI), Cerebral haemorrhage and Device dislocation. Event Cerebral infarction occurred on the next day (6-Jan-22), followed by Cerebral haemorrhage on the second day (7-Jan-22) and Focal epilepsy, Device dislocation and Cerebral haemorrhage occurred approximately 8 days (13-Jan-22) after a dose of mRNA-1273 vaccine. Computerised tomogram head done on 7-Jan-22 revealed Hemorrhage from cerebellum/vermis re involving expansion to fourth ventricle and also blood in the side ventricle right & hydrocephalus. Computerised tomogram head done on 13-Jan-22 revealed New severe bleeding in the drain-trajectory right frontal, hydrocephalus and previous cerebellar hemorrhage are globally consistent. The patient died 11 days (16-Jan-22) after vaccination. The reported cause of death was Cerebral haemorrhage. It is unknown if an autopsy was performed. The patient was noted to have received two doses from COMIRNATY approximately 7 months prior to current vaccination with mRNA1273 (Interchange of vaccine products). Patient's medical history of Throat cancer, basal cell carcinoma, breast cancer, smoking and Concurrent medical condition of Hypertension remains as a confounder for the fatal outcome. The benefit-risk relationship of mRNA-1273 is not affected by this report. Seriousness of the events retained as per Regulatory Authority report.. .Most recent FOLLOW-UP information incorporated above includes:.On 10-Mar-2022: Translation document received on 15-Mar-2022. Significant information received. Results of tests, events translated.
[redacted]		This case was initially received via European Medicines Agency (Reference number: [redacted] on 14-Feb-2022. The most recent information was received on 22-Feb-2022 and was forwarded to Moderna on 22-Feb-2022. .This regulatory authority case was reported by a physician and describes the occurrence of RESPIRATORY FAILURE (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA), PNEUMONIA (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA), CEREBROVASCULAR ACCIDENT (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA), COMA (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA), BLADDER SPHINCTER ATONY (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA), ACUTE KIDNEY INJURY (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA), SEPTIC SHOCK (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) and APHASIA (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) in an 87-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3006322) for COVID-19 vaccination. . .The patient's past medical history included Neurocognitive deficit (MMSE 13/30) on 01-Apr-2021..Previously administered products included for SARS-CoV-2 vaccination: COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03) on 02-Apr-2021 and COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03) on 23-Apr-2021..Past adverse reactions to the above products included No adverse event with COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03) and COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03)..Concurrent medical conditions included COPD, Hypertension arterial and Renal failure chronic..Concomitant products included AMLODIPINE BESILATE (NORVASC), POTASSIUM CANRENOATE (KANRENOL), TRAZODONE HYDROCHLORIDE (TRITTICO), QUETIAPINE and PIROXICAM (FOSTER [PIROXICAM]) for an unknown indication.. ..On 23-Nov-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On 21-Jan-2022, the patient experienced RESPIRATORY FAILURE (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death), PNEUMONIA (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death), CEREBROVASCULAR ACCIDENT (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death), COMA

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		(sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death), BLADDER SPHINCTER ATONY (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death), ACUTE KIDNEY INJURY (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death), SEPTIC SHOCK (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death) and APHASIA (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death). The patient died on 27-Jan-2022. The reported cause of death was Shock septic. An autopsy was not performed. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 21-Jan-2022, Angiogram cerebral: inconclusive (Inconclusive) Inconclusive..On 21-Jan-2022, Blood gases: inconclusive (Inconclusive) Inconclusive..On 21-Jan-2022, Blood test: inconclusive (Inconclusive) Inconclusive..On 21-Jan-2022, CSF culture: inconclusive (Inconclusive) Inconclusive..On 21-Jan-2022, Chest X-ray: inconclusive (Inconclusive) Inconclusive..On 21-Jan-2022, Computerised tomogram head: inconclusive (Inconclusive) Inconclusive..On 21-Jan-2022, Echocardiogram: inconclusive (Inconclusive) Inconclusive..On 21-Jan-2022, Electrocardiogram: inconclusive (Inconclusive) Inconclusive..On 21-Jan-2022, Electroencephalogram: inconclusive (Inconclusive) Inconclusive..On 21-Jan-2022, Physical examination: inconclusive (Inconclusive) Inconclusive..On 21-Jan-2022, SARS-CoV-2 test negative: inconclusive (Inconclusive) Inconclusive..On 22-Jan-2022, Blood culture: inconclusive (Inconclusive) Inconclusive..On 22-Jan-2022, Tracheal aspirate culture: inconclusive (Inconclusive) Inconclusive..On 25-Jan-2022, Specialist consultation: inconclusive (Inconclusive) Inconclusive.. . .The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown.. .For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.. .Treatment medication were not reported...Company comment: This regulatory case concerns an 87-year-old elderly male patient with medical history of COPD, hypertension arterial, renal failure chronic, neurocognitive deficit, and interchange of vaccine products (two doses of Comirnaty Covid19 vaccine), experienced the unexpected Fatal events Respiratory failure, Pneumonia, Cerebrovascular accident, Coma, bladder sphincter atony, Acute kidney injury, Septic shock, and Aphasia, one month twenty-nine days after a dose of mRNA-1273. The cause of death was reported as Septic shock. Autopsy was not performed. Advanced age of the patient could be a risk factor. Medical history of COPD, hypertension arterial, renal failure chronic could be confounding. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting.. .Most recent FOLLOW-UP information incorporated above includes:.On 22-Feb-2022: Added patient's medical history, lab data, concomitant medications, events (bilateral pneumonia, stroke, coma, bladder sphincter atony, renal failure acute, aphasia), updated seriousness, verbatim for events (respiration failure, septic shock) and deleted event (sopor)..On 07-Mar-2022: Non-significant follow up appended, Senders comment updated
[redacted]		This case was initially received via European Medicines Agency (Reference number:[redacted] on 14-Feb-2022. The most recent information was received on 22-Feb-2022 and was forwarded to Moderna on 22-Feb-2022. .This regulatory authority case was reported by a consumer and describes the occurrence of SARS-COV-2 TEST POSITIVE (Covid-19 infection), PYREXIA (hiti), PNEUMONIA (pneumonia bacterial), IMMUNE SYSTEM DISORDER (The immune system collapses), COVID-19 PNEUMONIA (Covid-19 pneumonia), RESPIRATORY FAILURE (Respiratory failure), DEEP VEIN THROMBOSIS (deep vein thrombosis), ORGAN FAILURE (Organ failure) and PULMONARY EMBOLISM (pulmonary embolism) in a 74-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. . .Co-suspect products included non-company products TOZINAMERAN (COMIRNATY) for COVID-19 immunisation and COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) for COVID-19 immunisation.. .No Medical History information was reported.. .On an unknown date, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form, TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form and first dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) (unknown route) 1 dosage form. On an unknown date, the patient experienced SARS-COV-2 TEST POSITIVE (Covid-19 infection) (seriousness criteria hospitalization and life threatening), PYREXIA (hiti) (seriousness criteria hospitalization and life threatening), PNEUMONIA (pneumonia bacterial) (seriousness criteria hospitalization and life threatening), IMMUNE SYSTEM DISORDER (The immune system collapses) (seriousness criteria hospitalization and life threatening), COVID-19 PNEUMONIA (Covid-19 pneumonia) (seriousness criteria hospitalization, medically significant and life threatening), RESPIRATORY FAILURE (Respiratory failure) (seriousness criteria death, hospitalization, medically significant and life

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		threatening), COVID-19 IMMUNISATION (A booster vaccination with a different vaccine), DEEP VEIN THROMBOSIS (deep vein thrombosis) (seriousness criteria hospitalization and life threatening), ORGAN FAILURE (Organ failure) (seriousness criteria death, hospitalization and life threatening) and PULMONARY EMBOLISM (pulmonary embolism) (seriousness criteria hospitalization and life threatening). The patient died on 10-Dec-2021. The reported cause of death was Respiratory failure and Organ failure. It is unknown if an autopsy was performed. At the time of death, SARS-COV-2 TEST POSITIVE (Covid-19 infection), PYREXIA (hiti), PNEUMONIA (pneumonia bacterial), IMMUNE SYSTEM DISORDER (The immune system collapses), COVID-19 PNEUMONIA (Covid-19 pneumonia), COVID-19 IMMUNISATION (A booster vaccination with a different vaccine), DEEP VEIN THROMBOSIS (deep vein thrombosis) and PULMONARY EMBOLISM (pulmonary embolism) outcome was unknown. . . . . .No concomitant products were reported.The patient was diagnosed with Covid-19 infection and Covid-19 pneumonia after the hospitalization on the 01/Dec/2021. He was also diagnosed with bacterial pneumonia couple of days later. Later the third infection was diagnosed, however they were not able to find the infection focus. The patient had 40 degree fever, embolism is diagnosed both in lungs and a DVT in his feet. No treatment information was reported.The organs start to fail and the cause of death is reported as respiratory failure..COMPANY COMMENT : This regulatory authority case concerns a 74-year-old male patient, with no medical history reported, who had fatal outcome with unexpected serious AESI events of SARS-COV-2 test positive (seriousness criteria hospitalization and life threatening), covid-19 pneumonia (seriousness criteria hospitalization and life threatening, medically significant), deep vein thrombosis (seriousness criteria hospitalization and life threatening), pulmonary embolism (seriousness criteria hospitalization and life threatening) and unexpected serious events of pyrexia ,pneumonia ,immune system disorder (seriousness criteria hospitalization and life threatening),respiratory failure ,organ failure (seriousness criteria hospitalization, death, and life threatening) .Patient received mRNA-1273 vaccine as the second dose of COVID-19 vaccination schedule that included a first dose of CHADOX 1 NCOV 19 (VAXZEVRIA) vaccine and a third dose with Tozinameran Interchange of vaccine products is noted. The patient died on 10-Dec-2021.Patient was diagnosed with Covid-19 infection and Covid-19 pneumonia after the hospitalization on on the 01/Dec/2021. He was also diagnosed with bacterial pneumonia few days later. Embolism is diagnosed both in lungs and a DVT in his feet. The reported cause of death is respiratory failure and organ failure. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 is not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 22-Feb-2022: Follow up received and new events added. Narrative updated. Cause of death updated to respiratory failure and organ failure, outcome updated.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 17-Feb-2022 and was forwarded to Moderna on 17-Feb-2022. .This regulatory authority case was reported by a physician and describes the occurrence of STAPHYLOCOCCAL SEPSIS (Staphylococcal sepsis), ATRIAL FIBRILLATION (Atrial fibrillation), ENDOTRACHEAL INTUBATION (Intubation NOS), RESPIRATORY FAILURE (Respiratory failure), TACHYCARDIA (Tachycardia), CARDIAC FAILURE (Cardiac failure aggravated) and RENAL FAILURE (Renal failure aggravated) in a 71-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. . .The patient's past medical history included Chronic renal failure, COPD, Heart failure, Emphysema and Myelomatosis (Immunosuppressed with daratumumab + bortezomib (Velcade) + dexamethasone, due to multiple myeloma.)..Previously administered products included for Vaccination: Comirnaty and Comirnaty..Past adverse reactions to the above products included No adverse event with Comirnaty and Comirnaty..Concomitant products included DARATUMUMAB, BORTEZOMIB and DEXAMETHASONE for Myelomatosis.. ..On 04-Oct-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 09-Oct-2021, the patient experienced ATRIAL FIBRILLATION (Atrial fibrillation) (seriousness criterion death), ENDOTRACHEAL INTUBATION (Intubation NOS) (seriousness criterion death), RESPIRATORY FAILURE (Respiratory failure) (seriousness criterion death), TACHYCARDIA (Tachycardia) (seriousness criterion death) and RENAL FAILURE (Renal failure aggravated) (seriousness criterion death). On an unknown date, the patient experienced STAPHYLOCOCCAL SEPSIS (Staphylococcal sepsis) (seriousness criterion death), COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) and CARDIAC FAILURE (Cardiac failure aggravated) (seriousness criterion death). The patient died on 22-Oct-2021. It is unknown if an autopsy was performed. At the time of death, COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) outcome was unknown. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 09-Oct-2021, Echocardiogram: ejection fraction in the 20s. Ejection fraction in the 20s...On 09-Oct-2021, X-ray: x-ray thorax found densification basal on the left X-ray thorax found densification basal

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		on the left side...On 10-Oct-2021, Echocardiogram: improvement of left ventricular function in sinus Improvement of left ventricular function in sinus rhythm. Left ventricular ejection fraction: 35-40 percent...On 13-Oct-2021, Glomerular filtration rate: 17 17 millilitre per minute per 1.73 square metre..On 17-Oct-2021, Magnetic resonance imaging: mri caput noted two small point-shaped cerebral in MRI caput noted two small point-shaped cerebral infarctions, one of which with a slight connected subarachnoidal hematoma. This could not explain the comatose state...On 22-Oct-2021, Body temperature: 40 40 degree Celsius.. . .For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered STAPHYLOCOCCAL SEPSIS (Staphylococcal sepsis), ATRIAL FIBRILLATION (Atrial fibrillation), ENDOTRACHEAL INTUBATION (Intubation NOS), RESPIRATORY FAILURE (Respiratory failure), TACHYCARDIA (Tachycardia), CARDIAC FAILURE (Cardiac failure aggravated) and RENAL FAILURE (Renal failure aggravated) to be possibly related. No further causality assessment was provided for COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine). . .No treatment medication details were provided. ..Company comment:.This regulatory authority case concerns a 71-year-old male patient, with relevant medical history of myelomatosis under immunosuppressed treatment, heart failure, COPD, emphysema and CRF, who experienced the fatal AESI of respiratory, cardiac and renal failure, atrial fibrillation and serious (death) unexpected events of staphylococcal sepsis, tachycardia and endotracheal intubation after the third dose of mRNA-1273. It was reported that the patient was hospitalized due to clinical pulmonary edema, respiratory failure and kidney failure (aggravated) 6 days after receiving the mRNA-1273 vaccine. Then, the patient was intubated due to respiratory failure, electrical cardioversion was reported. The patient did not responded to repeated awakening attempts and developed a Staphylococcal sepsis. The patient died 19 days after the third dose of mRNA-1273. No information regarding if an autopsy was performed. Cause of death was not further specified. Patient's underlying diseases remain contributing factors. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 17-Feb-2022 and was forwarded to Moderna on 17-Feb-2022. .This regulatory authority case was reported by a physician and describes the occurrence of COVID-19 PNEUMONIA (SARS-CoV-2 pneumonia) and VACCINATION FAILURE (Vaccination failure) in an 89-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004834) for COVID-19 vaccination. . .Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 vaccination.. .The patient's past medical history included Aneurysm of aorta, Carotid artery atheroma, Hypertension arterial, Infarct myocardial in 2017, Artificial cardiac pacemaker wearer in 2015, AFib and Coronary arterial stent insertion in 2017..Concurrent medical conditions included Tabaquism..Concomitant products included FINASTERIDE for Disorder urinary tract, PANTOPRAZOLE for Gastritis prophylaxis, BISOPROLOL FUMARATE (BISOCE) for Hypertension arterial, ACETYLSALICYLATE LYSINE (KARDEGIC) and ATORVASTATIN CALCIUM (TAHOR) for Prevention, ENOXAPARIN SODIUM (LOVENOX HP) for Thromboembolism prophylaxis.. .On 06-Mar-2021, the patient received dose of TOZINAMERAN (COMIRNATY) (Intramuscular) 2 dosage form..On 01-Apr-2021, received dose of TOZINAMERAN (COMIRNATY) (Intramuscular) dosage was changed to 2 dosage form..On 29-Sep-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 07-Jan-2022, the patient experienced COVID-19 PNEUMONIA (SARS-CoV-2 pneumonia) (seriousness criteria death and hospitalization) and VACCINATION FAILURE (Vaccination failure) (seriousness criteria death and hospitalization). The patient died on 15-Jan-2022. It is unknown if an autopsy was performed. . . .For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.. .No treatment information was provided...Company comment:.This Fatal Regulatory Authority case concerns a 89-year-old, male patient, with medical history of tabaquism, hypertension, atrial fibrillation and myocardial infarction, who experienced the unexpected, serious (death/hospitalization) and AESI of COVID-19 pneumonia. Vaccination failure was also reported, however, the patient received previously as first and second dose of his COVID-19 vaccination schedule two doses of Cominarty's COVID-19 vaccine. The event occurred 3 months and 9 days after receiving a dose of mRNA-1273 vaccine, reported as R1 and he died 8 days after. Cause of death was not reported. Autopsy report is not available. Patient's age, gender, medical history of tabaquism, hypertension, atrial fibrillation and myocardial infarction remain as confounders. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.
[redacted]		This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 16-Feb-2022. The most recent information was received on 11-Mar-2022 and was forwarded to Moderna on 17-Mar-2022. . This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a (physician), was received via the PMDA (Ref, [redacted]. On 11-Mar-2022, follow-up information was received from a

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		physician. Childhood epileptic seizure was controlled by treatment with oral treatment. The patient made regular visits to the psychiatric department of the reporting hospital for profound intellectual disability. On 01-Jul-2021, the patient received the 1st dose of coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 29-Jul-2021, the patient received the 2nd dose of coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, body temperature before the vaccination: 35.9 degrees Celsius. On 10-Feb-2022, at 14:00, the patient received the 3rd vaccination with this vaccine. There was no particular problem after the vaccination. On 11-Feb-2022, from the morning, the patient had frequent watery stools. The patient vomited several times from the night to before dawn on 12-Feb-2022. On 12-Feb-2021, before dawn, after vomiting, pyrexia developed with choking. At 09:30, the patient visited the reporting hospital. Pyrexia of 38.7 degrees Celsius was noted, SpO2 was 97%, RR was 20/min, and crackles were noted in the right lung field. Blood pressure was unmeasurable, radial A was palpable feebly, HR was 110-140, and the patient was awake. Administration of glucose lactated ringer's solution 500 mL was performed. Although videoendoscopic evaluation of swallowing (VE) showed no obvious aspiration, there was mild cough. In addition to severe dehydration and decreased blood pressure due to gastroenteritis, pneumonia aspiration due to vomiting was suspected, and the patient was taken to another hospital by ambulance. During transportation, the patient vomited heavily and lost consciousness. Although ambulance workers performed cardiopulmonary resuscitation, on arrival at the hospital, the patient was in a state of cardio-respiratory arrest. Endotracheal intubation was performed. The tubes were also covered by vomit. Cardiotonic drugs were administered, but there was no response, and the patient was confirmed dead. No autopsy was performed. The cause of death was an unknown intrinsic factor. The outcome of pyrexia, gastroenteritis, blood pressure decreased, suspected aspiration pneumonia, and loss of consciousness was unknown. The outcome of diarrhea, vomiting, severe dehydration, and cardio-respiratory was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: Since this event developed from the next day of the vaccination, the occurrence of the adverse events is temporally related to timing of administration of this vaccine. The patient had taken concomitant drugs for a long time before the vaccination with this vaccine, so the occurrence of adverse events is not related to concomitant drugs. Because bowel movement disturbance may have been related to the occurrence of adverse events, the occurrence of adverse events is related to pathogenic factors of bowel movement disease. It is difficult to determine whether the adverse events of diarrhea and vomiting were caused by the vaccination with this vaccine. Bowel movement disturbance was present before the vaccination. Regarding death, the patient had mild cough although history of left pyothorax and subsequent videoendoscopic evaluation of swallowing (VE) showed no apparent aspiration, and there may have been latent decreased swallowing function. Follow-up received on 11-MAR-2022 Updated: Patient Information, Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments .Company Comment: Although dehydration developed after the administration of ELASOMERAN, influence of contingent event can also be considered.
[redacted]		This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 16-Feb-2022. The most recent information was received on 16-Mar-2022 and was forwarded to Moderna on 24-Mar-2022. .This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, [redacted]. On 16-Mar-2022, follow-up information was received from a physician. On an unknown date, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 12-Feb-2022, the patient received the 3rd vaccination with this vaccine. On 13-Feb-2022, around 16:00, consciousness disturbed developed. The patient was found collapsed and was transported by ambulance. The patient was suspected to have developed heat illness in a hot environment due to difficulty moving due to an unforeseen accident or a preceding disease. The patient was already in multi-organ failure, in shock, and difficult to save the patients life. CT showed the possibility of multiple cerebral infarctions but could not be confirmed. There was a suspected cerebral infarction due to chronic atrial fibrillation. On 14-Feb-2022, the patient was confirmed dead. The cause of death was heat illness. No autopsy was performed. The outcome of consciousness disturbed, possible multiple cerebral infarctions, difficulty in moving, suspected heat illness, multi-organ failure and shock was reported as fatal. No follow-up investigation will be made. ..Reporter's comment: The causal relationship between the progress and this vaccination is unknown. There is a possibility that cerebral infarction caused the difficulty in moving, resulting in heat illness, but the possibilities that the cause was atrial fibrillation, that the cerebral infarction was a result rather than a cause, and that the patient had no cerebral infarction from the beginning were also cannot be ruled out. Other factors include the possibility of suspected cerebral infarction due to chronic atrial fibrillation. The relationship between cause of death and adverse

Case ID	WW Identifier	Narrative Complete
		events is unknown. The cause of the heat illness was a fall in a bedrock bath facility, which may have been caused by cerebral infarction. Since it cannot be denied that cerebral infarction may be caused by thrombosis or chronic atrial fibrillation due to vaccination with this vaccine, it is unclear whether the occurrence of adverse events is temporally related to the timing of administration of this vaccine. The occurrence of adverse events may be associated with pathological factors of chronic atrial fibrillation. Neither the presence or absence of cerebral infarction nor the association of cerebral infarction with this vaccination, if any, can be determined. ..Follow-up received on 16-MAR-2022 Updated: Patient Information, Other Relevant History, Lab Data, Event Information, Narrative, Reporter Comments ..LP Company Comment: As for heat illness, the event developed after the administration of ELASOMERAN, but it could also be due to the patient's environment, or other influences. As for cerebral infarction, the event developed after the administration of ELASOMERAN, but it could also be due to the patient's medical history or concurrent events, or other influences...Company comment: .This spontaneous case concerns a 76-year-old, male patient with medical history of Diabetes mellitus and Atrial fibrillation, who experienced unexpected serious events of Cerebral infarction (seriousness criterion: Fatal, Hospitalisation, Medically significant), Heat illness (seriousness criterion: Fatal, Hospitalisation, Medically significant), Multiple organ dysfunction syndrome (seriousness criterion: Fatal, Medically significant), Shock (seriousness criterion: Fatal, Medically significant), Movement disorder (seriousness criterion: Fatal, Hospitalization) and Altered state of consciousness (seriousness criterion: Fatal, Hospitalisation, Medically significant). It was reported that a day after receiving the mRNA-1273 vaccine (as third dose), the patient developed disturbed consciousness. The patient was found collapsed and was transported by ambulance. The patient was suspected to had developed heat illness in a hot environment due to difficulty moving due to an unforeseen accident or a preceding disease. The patient was already in multi-organ failure and shock. CT showed the possibility of multiple cerebral infarctions due to chronic atrial fibrillation, but it could not be confirmed. The cause of death was heat illness and no autopsy was performed. The outcome of consciousness disturbed, possible multiple cerebral infarctions, difficulty in moving, suspected heat illness, multi-organ failure and shock was reported as fatal. Underlying medical history of atrial fibrillation remains a major confounder for Cerebral infarction which could contribute to movement disorder and altered state of consciousness. The patient's elderly age remains an additional confounder. Having in mind that this patient received Comrinaty vaccine prior to vaccination with the company product, Interchange of vaccine products should have been considered in this specific case. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.
[redacted]		This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 17-Feb-2022. The most recent information was received on 15-Mar-2022 and was forwarded to Moderna on 23-Mar-2022. .This case was reported by a pharmacist via the Drug Information Center. On 15-Mar-2022, follow-up information was received from a physician. Respiratory arrest was assessed as serious by the MAH. On an unknown date, the patient received the 1st dose of coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, the patient received the 2nd dose of coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 15-Feb-2022, around 17:00, the patient received the 3rd vaccination with this vaccine. There was no change in the physical condition immediately after that. On 16-Feb-2022, at 00:55, when a nurse went to check on the patient, body temperature was 37.3 degrees Celsius. SpO2 was 93% under 2L of O2. Large amount of white viscous sputum could be aspirated. There was no remarkable change. At 04:16, in the morning, when a nurse went to check on the patient for the injection, the patient was found in respiratory arrest. The patient refused resuscitation (DNAR), so life-saving measures were not taken. This case was reported to a physician. At 08:10, the patient was confirmed dead by the physician. The cause of death was prostate cancer. No necropsy was performed. The outcome of respiratory arrest, large amount of white viscous sputum and pyrexia was unknown. No follow-up investigation will be made. Reporter comments continuation: The occurrence of adverse events is related to pathological factors of prostate cancer because the patient's general condition was likely to be unstable due to diseases. The patient originally had advanced prostate cancer, and it can be assumed that the general condition was prone to instability. Therefore, administration of this vaccine is not necessarily the cause, but on the other hand, vitals such as blood pressure were stable until the previous day, and it was difficult to determine the direct cause of death. Adverse events associated with administration of this vaccine may have developed. There was no relationship between cause of death and adverse events. Follow-up received on 15-MAR-2022 Updated: Reporter Information, Patient Information, Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments .Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.

Case ID	WW Identifier	Narrative Complete
[redacted]	[redacted]	This case was initially received via European Medicines Agency (Reference number: [redacted] on 17-Feb-2022. The most recent information was received on 07-Mar-2022 and was forwarded to Moderna on 07-Mar-2022. .This regulatory authority case was reported by a physician and describes the occurrence of ANURIA (anuria, urinary septic shock with MOF, cardiopathic, diabetic, AOCP), MULTIPLE ORGAN DYSFUNCTION SYNDROME (anuria, urinary septic shock with MOF, cardiopathic, diabetic, AOCP) and SEPTIC SHOCK (anuria, urinary septic shock with MOF, cardiopathic, diabetic, AOCP) in a 74-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005887) for COVID-19 vaccination. . .The patient's past medical history included Respiration failure on 01-Nov-2015, Amnestic disorder, Recovered smoker (end date- 01-Jan-1992), Septicaemia (01/10/2021: admitted again for septicemia) on 01-Jan-2020, Diaphragmatic hernia, Obstructive arteriosclerosis of lower extremities on 01-Sep-2021, Aortic valve replacement, Lactic acidosis (iatrogenic) on 01-Aug-2015, Hypertensive heart disease, Anemia (severe enteric loss anemia) on 01-Aug-2015, Hyperuricaemia, Hepatic steatosis on 01-Jan-2010, Acute pulmonary oedema on 01-Jan-2007, Cerebral infarct on 01-Jan-2007 and Femur fracture (dx) on 01-Jan-1972..Previously administered products included for SARS-CoV-2 immunisation: COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03) on 06-Apr-2021 and COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03) on 27-Apr-2021..Past adverse reactions to the above products included No adverse event with COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03) and COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03)..Concurrent medical conditions included Diabetic retinopathy, Insulin-requiring type 2 diabetes mellitus on 01-Jan-2007, Hypertension arterial and Atrial fibrillation..Concomitant products included INSULIN GLARGINE (TOUJEO), ATORVASTATIN CALCIUM (TORVAST), ACETYLSALICYLIC ACID (CARDIOASPIRIN), DIGOXIN (LANOXIN), APIXABAN (ELIQUIS), FUROSEMIDE (LASIX P), SERTRALINE, POTASSIUM CANRENOATE (KANRENOL), BISOPROLOL FUMARATE (SEQUACOR), LANSOPRAZOLE (LANSOX) and INSULIN ASPART (NOVORAPID) for an unknown indication.. ..On 22-Nov-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On 30-Jan-2022, the patient experienced ANURIA (anuria, urinary septic shock with MOF, cardiopathic, diabetic, AOCP) (seriousness criterion death), MULTIPLE ORGAN DYSFUNCTION SYNDROME (anuria, urinary septic shock with MOF, cardiopathic, diabetic, AOCP) (seriousness criterion death) and SEPTIC SHOCK (anuria, urinary septic shock with MOF, cardiopathic, diabetic, AOCP) (seriousness criterion death). The patient died on 10-Feb-2022. The reported cause of death was Shock septic. An autopsy was not performed. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 30-Jan-2022, Blood test: inconclusive (Inconclusive) Inconclusive..On 30-Jan-2022, Chest X-ray: inconclusive (Inconclusive) Inconclusive..On 30-Jan-2022, SARS-CoV-2 test negative: inconclusive (Inconclusive) Inconclusive..On 30-Jan-2022, Vital signs measurement: inconclusive (Inconclusive) Inconclusive..On 31-Jan-2022, Blood gases: inconclusive (Inconclusive) Inconclusive..On an unknown date, Ultrasound scan: inconclusive (Inconclusive) Inconclusive.. . .For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.. .Reporter states first dose on 06/04/2021 comirnaty vaccine lot: et7205 sc: 31/07/2021, the second dose on 27/04/2021 comirnaty vaccine lot: ex3599 sc: 31/08/2021. Concomitant pathologies includes diabetes mellitus, heart disease and aocp...Company Comment: This is a Regulatory case concerning a 74-year-old male patient with interchange of vaccine administration (COVID-19 vaccine, 2 doses of Comirnaty 6-7 months (interval of 21 days) prior to mRNA-1273 dose and medical history of Septicaemia (recurrence: 2020 & Oct 2021), Obstructive arteriosclerosis of lower extremities (2021), Aortic valve replacement, Severe enteric loss anemia (2015), Hepatic steatosis (2010), Hyperuricaemia, Acute pulmonary oedema (2007), Cerebral infarct (2007), and concurrent Type 2 diabetes mellitus (15y), Diabetic retinopathy, Hypertension arterial, Atrial fibrillation, Heart disease and AOCP. The patient experienced the serious fatal unexpected events of Anuria (AESI), Multiple Organ Dysfunction Syndrome and Septic shock. The events occurred approximately 2 months 9 days after a dose of mRNA-1273 received as the third dose for COVID-19 Vaccination. The patient died on 10-Feb-2022 (11 days after events onset). The reported cause of death was Shock septic. An autopsy was not performed. Diagnostic workup (Blood test, Chest X-ray, Vital signs, blood gases) was reported with inconclusive results, however an urinary origin of the septic shock was described. Treatment information was not provided. The increased risk of developing infections and sepsis due to type 2 diabetes remains a confounder. Suggestive urinary tract infection could be contributory for septic shock. Septic shock is a contributing cause of MODS and anuria. Patient's advanced age, vast comorbidities and heart disease remain as confounders and increase risk for fatal outcome. Moreover case could be confounded by polypharmacy. The benefit-risk relationship of COVID-19 Vaccine Moderna (mRNA-1273) is not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 04-Mar-2022: Follow Up received with Non-Significant

Case ID	WW Identifier	Narrative Complete
		information..On 07-Mar-2022: Follow up received contains medical history, concomitant medications and event details.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 22-Feb-2022 and was forwarded to Moderna on 22-Feb-2022. .This regulatory authority case was reported by a physician and describes the occurrence of CIRCULATORY COLLAPSE (Circulatory collapse) and CARDIAC FAILURE CONGESTIVE (Bi-ventricular failure) in a 58-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3006273) for COVID-19 vaccination. . .The patient's past medical history included Overweight..Previously administered products included for Vaccination: Spikevax; for Product used for unknown indication: Comirnaty..Past adverse reactions to the above products included No adverse event with Comirnaty and Spikevax..Concurrent medical conditions included Hypercholesterolemia and Hypertension.. ..On 17-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced CIRCULATORY COLLAPSE (Circulatory collapse) (seriousness criteria death and hospitalization) and CARDIAC FAILURE CONGESTIVE (Bi-ventricular failure) (seriousness criteria death and hospitalization). The patient died on 02-Feb-2022. An autopsy was not performed. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.In 2022, Blood test: abnormal (abnormal) Perimyocarditis was a differential diagnosis, but MRI findings and blood tests indicate in the direction of AL amyloidosis. It is not specified in the report which blood test were performed..In 2022, Magnetic resonance imaging: abnormal (abnormal) Perimyocarditis was a differential diagnosis, but MRI findings and blood tests indicate at this point in the direction of AL amyloidosis.. . .For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered CIRCULATORY COLLAPSE (Circulatory collapse) and CARDIAC FAILURE CONGESTIVE (Bi-ventricular failure) to be possibly related. . .No concomitant medications were reported..No treatment details were reported...Company Comment - This regulatory authority case concerns a 58 year old male patient with medical history of hypertension, who experienced the serious unexpected events of circulatory collapse and cardiac failure congestive. The events occurred on an unknown date after a dose of mRNA-1273 vaccine, considered as the third dose of his COVID-19 vaccination schedule. The outcome was fatal and resulted in death. Patient's medical history of hypertension remains a confounder. The rechallenge was not applicable as there are no plans for future dosing. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 22-Feb-2022 and was forwarded to Moderna on 22-Feb-2022. .This regulatory authority case was reported by a physician and describes the occurrence of DEATH (cause of death unknown) in a 57-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004233) for COVID-19 vaccination. . .Patient is allergic to penicillin. .Previously administered products included for Prophylactic vaccination: COMIRNATY on 19-May-2021 and Comirnaty BNT162b2 on 25-Jun-2021..Past adverse reactions to the above products included No adverse event with COMIRNATY and Comirnaty BNT162b2..Concurrent medical conditions included Hypertension.. ..On 22-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 3 dosage form. Death occurred on 06-Jan-2022 The patient died on 06-Jan-2022. The cause of death was not reported. It is unknown if an autopsy was performed. . . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .Concomitant medications were not provided..Treatment information was not provided..On 22-Dec-2021 patient had taken COVID-19 booster vaccination with Spikevax..Patient had no side effects with 2 doses of Comirnaty...Company comment:.This Fatal Regulatory Authority case concerns a 57-year-old, male patient, with medical history of hypertension and penicillin allergy, who experienced the unexpected, serious event of death. The patient died 15 days after he received a dose of mRNA-1273 vaccine, considered as the third dose of his COVID-19 vaccination schedule, as he received as first and second dose two doses of Cominarty's COVID-19 vaccine. Cause of death was unknown. Autopsy report is not available. The medical history of hypertension penicillin allergy remain as confounders. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.
[redacted]		This case was initially received via United Kingdom MHRA (Reference number: [redacted] on 22-Feb-2022. The most recent information was received on 06-Mar-2022 and was forwarded to Moderna on 06-Mar-2022. .This regulatory authority case was reported by a consumer and describes the occurrence of CEREBRAL HAEMORRHAGE (Spontaneous brain haemorrage) in a 48-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. . .Patient was fit and well and was not on any other medication, nor did he use any drugs, ever. .Previously administered products included for COVID-19 vaccination: SARS-COV-2 VIRUS and SARS-COV-2 VIRUS..Past adverse reactions to the above products included No adverse event with SARS-COV-2 VIRUS and

Case ID	WW Identifier	Narrative Complete
		SARS-COV-2 VIRUS.. ..On 19-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 01-Jan-2022, the patient experienced CEREBRAL HAEMORRHAGE (Spontaneous brain haemorrage) (seriousness criterion death) and HEADACHE (Headache). On an unknown date, the patient experienced PAIN IN EXTREMITY (Pain in extremity). The patient died on 01-Jan-2022. The reported cause of death was Haemorrhage brain. An autopsy was performed, but no results were provided. At the time of death, HEADACHE (Headache) and PAIN IN EXTREMITY (Pain in extremity) had not resolved. . . . . .Dose 3c..As Reported: Haemorrhage brain and headache. 2 weeks after the Moderna they got a severe headache, went to sleep and never woke up. The coroner's report was a brain haemorrhage. Requested FU received 03/03/2022: A post-mortem was performed after the death of patient and his body was kept at the Hospital. When the person from the coroner's office called, they said it was a spontaneous subarachnoid haemorrhage. Patient had had 2 doses and then the booster on 19th December 2021. So, all in all he had had 3. Apart from a sore arm after the injection, he was fine. Reporter gave consent to contact the medical practices if need to and have attached the death certificate...Company comment: This regulatory case concerns a 48-year-old male patient with no reported medical history, who experienced the serious (death), unexpected event of Cerebral haemorrhage (reported as Spontaneous brain haemorrhage) 13 days after receiving the booster dose of mRNA-1273 vaccine. Patient had severe headache 2 weeks after receiving mRNA-1273 vaccine, went to sleep from which the patient never recovered. Autopsy report revealed the cause of death to be spontaneous subarachnoid haemorrhage. Patient had received 2 doses of Moderna vaccine before this booster dose. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. . .Most recent FOLLOW-UP information incorporated above includes:.On 06-Mar-2022: Significant follow-up received on 06-MAR-2022, relevant history, Autopsy details, Events and narrative updated.
[redacted]	[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 21-Feb-2022 and was forwarded to Moderna on 21-Feb-2022. .This regulatory authority case was reported by a pharmacist and describes the occurrence of IMMUNE THROMBOCYTOPENIA (autoimmune Thrombocytopenia) and CEREBRAL HAEMORRHAGE (Cerebral haemorrhage) in a 62-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 016G21A) for COVID-19 vaccination. . .Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 vaccination.. .The patient's past medical history included Neoplasm prostate (PROSTATE ADENOCARCINOMA T2 N1, SUSPECION OF BONE METASTASIS) in February 2021.. .On 01-Apr-2021, the patient received first dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form..On 22-Apr-2021, received second dose of TOZINAMERAN (COMIRNATY) (unknown route) dosage was changed to 1 dosage form..On 22-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, the patient experienced IMMUNE THROMBOCYTOPENIA (autoimmune Thrombocytopenia) (seriousness criterion death). an unknown date, the patient experienced CEREBRAL HAEMORRHAGE (Cerebral haemorrhage) (seriousness criterion death). The patient died on 07-Jan-2022. It is unknown if an autopsy was performed. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 01-Jan-2022, Laboratory test: severe thrombocytopenia with elevated d-dimer laboratory finding of severe thrombocytopenia (18x10.3ul) with elevated D-Dimer (34400ug/L), elevated LDH (4433IU/L) and hypertransaminsamia (GOT 361Ui/L; GPT 56IU/L)...On 05-Jan-2022, Chest X-ray: non-thickened hila, no pulmonary infiltrates - Chest X-ray 1/5/22: Well inspired, well turned, centered. CTI<0.5, non-thickened hila, no pulmonary infiltrates or pleural effusion...On 06-Jan-2022, Scan brain: large intraparenchymal hemorrhage Large intraparenchymal hemorrhage in the right cerebral hemisphere, mostly at the level of the frontal lobe, about 6 x 4 cm in size in the axial plane. A deviation from the midline of about 7mm to the left is taking place. There are small dense satellite foci in this same frontal lobe and in the ipsilateral temporal lobe, as well as in the left frontal lobe of up to 4mm, in the latter location. The hemorrhage has opened to the ventricular system occupying most of the body of the right lateral ventricle, the dependent segments of the contralateral, the third and fourth ventricles and through the holes of Luschka and Magendie they exit to the perimesencephalic cisterns, erasing them. It is difficult to assess whether there is transforaminal descent for this reason. Conclution: Intraparenchymal hemorrhages, the largest in the right hemiencephalon, open to the ventricular system and the subarachnoid space... . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .No concomitant medication information was provided..No treatment medication was provided...Company comment: This is a regulatory case concerning a 62 year-old, male patient with a history of Neoplasm prostate (diagnosed in february 2021 and suspicion of bone metastasis), who experienced the serious Fatal unexpected, AESI of Immune thrombocytopenia and Cerebral haemorrhage, approximately 15 to 16 days after the mRNA-1273 vaccine, received as third dose of the COVID-19 vaccination. Lab tests performed showed severe thrombocytopenia (18x10.3ul) with elevated D-Dimer (34400ug/L),

Case ID	WW Identifier	Narrative Complete
		elevated LDH (4433IU/L) and hypertransaminsamia (GOT 361Ui/L; GPT 56IU/L). A brain scan diagnosed a Large intraparenchymal hemorrhage in the right cerebral hemisphere, open to the ventricular system and the subarachnoid space. It is unknown whether an autopsy was performed, cause of death was not further specified. The patient died 16 days after vaccination. Additionally, Interchange of vaccine products (vaccination with two doses of COVID-19 vaccine BioNTech approximately 8 months prior) was noted in the case. The mentioned medical history remains as a confounder for the fatal outcome. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 23-Feb-2022 and was forwarded to Moderna on 23-Feb-2022. .This regulatory authority case was reported by a physician and describes the occurrence of CONDITION AGGRAVATED (Condition worsened), DECREASED APPETITE (Appetite lost), WEIGHT DECREASED (Weight loss) and VOMITING (Vomiting) in an 81-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004235) for COVID-19 vaccination. . .Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for Prophylactic vaccination.. .Previously administered products included for COVID-19 vaccination: COMIRNATY on 29-Apr-2021..Past adverse reactions to the above products included No adverse event with COMIRNATY.. .On 10-Jun-2021, the patient received dose of TOZINAMERAN (COMIRNATY) (unknown route) 2 dosage form..On 06-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. In August 2021, the patient experienced DECREASED APPETITE (Appetite lost) (seriousness criterion death), WEIGHT DECREASED (Weight loss) (seriousness criterion death) and VOMITING (Vomiting) (seriousness criterion death). In October 2021, the patient experienced CONDITION AGGRAVATED (Condition worsened) (seriousness criterion death). The cause of death was not reported. It is unknown if an autopsy was performed. . . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .No concomitant medication was reported..Comirnaty strength was 0.3 millilitre..The patient received Spikevax booster vaccination..Date of death was not reported..No treatment information was reported.
[redacted]		This case was initially received via European Medicines Agency (Reference number: [redacted] on 23-Feb-2022. The most recent information was received on 05-May-2022 and was forwarded to Moderna on 05-May-2022. .This regulatory authority case was reported by a physician and describes the occurrence of VACCINATION FAILURE (Vaccination failure) and DRUG INEFFECTIVE (Drug ineffective) in a 66-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214022) for COVID-19 vaccination. . .Co-suspect products included non-company products CASIRIVIMAB, IMDEVIMAB (RONAPREVE) for COVID-19 prophylaxis, TOZINAMERAN (COMIRNATY) for COVID-19 vaccination, OBINUTUZUMAB (GAZYVARO) for Non-Hodgkin's lymphoma and LENALIDOMIDE (REVLIMID) for Non-Hodgkin's lymphoma.. .Concurrent medical conditions included Linea alba hernia in 1986, Non-Hodgkin's lymphoma in March 2017, Psoriasis, Hypercholesterolaemia, Cyst, Carpal tunnel syndrome, Maxillary sinusitis, Aortic incompetence in May 2021 and Tendinopathy.. .On 16-Feb-2021, the patient started OBINUTUZUMAB (GAZYVARO) (Oral) 1000 milligram..On 10-Mar-2021, the patient received first dose of TOZINAMERAN (COMIRNATY) (Intramuscular) 1 dosage form..On 07-Apr-2021, received second dose of TOZINAMERAN (COMIRNATY) (Intramuscular) dosage was changed to 1 dosage form..On 13-Sep-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form..On 27-Sep-2021, the patient started LENALIDOMIDE (REVLIMID) (Oral) 20 milligram..On 25-Oct-2021, the patient started CASIRIVIMAB, IMDEVIMAB (RONAPREVE) (Intravenous) 600 milligram. On an unknown date, the patient experienced VACCINATION FAILURE (Vaccination failure) (seriousness criterion death). an unknown date, the patient experienced DRUG INEFFECTIVE (Drug ineffective) (seriousness criterion death). The reported cause of death was Drug ineffective and Vaccination failure. It is unknown if an autopsy was performed. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 04-Jan-2022, SARS-CoV-2 test: positive (Positive) Positive.. . .For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.. .Concomitant product use was not provided by the reporter...Treatment information was not provided...Dosage text given as R1...Company comment: This is a Vaccination failure Regulatory Authority case concerning a 66-year-old male patient, with relevant medical history of non-Hodgkin´s lymphoma and aortic incompetence. Patient died 106 days after a dose of mRNA-1273 vaccine. The reported cause of death was Drug ineffective and Vaccination failure. It is unknown if an autopsy was performed. SARS-CoV-2 test with positive result was reported approximately 3 months and 20 days after mRNA-1273 vaccine. Medical history of non-Hodgkin´s lymphoma and aortic incompetence could be confounders for the fatal outcome. Co-suspect products included non-company products: Casirivimab, Imdevimab, Obinutuzumab and Lenalidomide. Primary vaccination completed with Pfizer vaccine, which remains

Case ID	WW Identifier	Narrative Complete
		as a co-suspect product. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 05-May-2022: Follow Up received with significant information as Co-suspect drug added.
[redacted]		This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 22-Feb-2022. The most recent information was received on 17-Mar-2022 and was forwarded to Moderna on 24-Mar-2022. .This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, [redacted] On 17-Mar-2022, follow-up information was received from a physician. The vaccine recipient had a history of cerebral infarction and was being followed up for hypertension at the time of the medical examination. The patient did not receive any medical treatment such as oral medication. On 14-Jun-2021, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 05-Jul-2021, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, body temperature before the vaccination: 35.7 degrees Celsius. On 21-Feb-2022, around 11:00, the patient received the 3rd vaccination with this vaccine. On 22-Feb-2022, at 00:30, the patient was found lying face down at home. AED was used, but the patient had no response. The patient was transported by ambulance. At 01:10, the patient was in a state of cardio-respiratory arrest. At 02:29, the patient was confirmed dead at the same hospital. Bruise on the head and epistaxis were noted. Autopsy was not performed. The outcome of cardio-respiratory arrest was reported as fatal. The outcome of bruise on the head and epistaxis was unknown. No follow-up investigation will be made. Follow-up received on 17-MAR-2022 Updated: Reporter Information, Event Information, Narrative, Reporter Comments .Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
[redacted]		This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 24-Feb-2022. The most recent information was received on 14-Mar-2022 and was forwarded to Moderna on 22-Mar-2022. .This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a pharmacist, was received via the PMDA (Ref, [redacted]. On 14-Mar-2022, follow-up information was received from a physician. On an unknown date, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 17-Feb-2022, the patient received the 3rd dose of this vaccine. On 18-Feb-2022, at 18:30, it was the last time when the patient was confirmed healthy. Around 19:00, lethal arrythmia developed. A family member found the patient taking a bath and called an ambulance. When the ambulance team made contact, the patient was in a state of cardio-respiratory arrest. The initial waveform was asystole. At 19:40, the patient entered the emergency outpatient department of the reporting hospital. At 19:48, adrenaline 1 mg/mL was injected intravenously. At 19:52, adrenaline 1 mg/mL was injected intravenously. At 19:57, adrenaline 1 mg/mL was injected intravenously. At 20:00, adrenaline 1 mg/mL was injected intravenously. At 20:03, adrenaline 1 mg/mL was injected intravenously. At 20:06, adrenaline 1 mg/mL was injected intravenously. At 20:10, adrenaline 1 mg/mL was injected intravenously. Though intravenous injections were carried out seven times in total, the spontaneous circulation was not returned. At 20:11, death was pronounced. At 20:24, the obvious cause of death could not be indicated in diagnostic imaging CT at the time of death. At 20:41, an autopsy was performed. According to the postmortem certificate, the cause of death was lethal arrhythmia, and the time from onset to death was short. No autopsy was performed. The outcome of lethal arrythmia and cardio-respiratory arrest (CPA) was reported as fatal. No follow-up investigation will be made. Follow-up received on 14-MAR-2022 Updated: Other Relevant History, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
[redacted]		This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 24-Feb-2022. The most recent information was received on 17-Mar-2022 and was forwarded to Moderna on 24-Mar-2022. .This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, [redacted] On 17-Mar-2022, follow-up information was received from a physician. The patient made regular visits to another hospital for diabetes mellitus, hypertension, and late effects of cerebral infarction. On 27-Jun-2021, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 18-Jul-2021, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 15-Feb-2022, the patient made a regular visit to a hospital. There were no particular abnormalities. On 17-Feb-2022, the patient did not have dinner due to physical deconditioning. There were no symptoms such as pyrexia. On 18-Feb-2022, the patient had a light meal. On 20-Feb-2022, the patient received the 3rd vaccination with this

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		vaccine. At night, the patient had poriomania. On 21-Feb-2022, in the morning, the family member confirmed traumatic injury on the head and right lower leg. The patient had no particular symptoms until around noon. After 18:00, the patient was sitting leaning against the bed and did not respond to calls. At 18:31, an ambulance was called. At 18:44, the ambulance team arrived and confirmed the patient's cardio-respiratory arrest. Cardiopulmonary resuscitation was started for asystole, and the patient was transported to the reporting hospital. Administration of adrenaline 2A was performed. At 19:03, the patient was race to the reporting hospital. The patient made an initial visit to the reporting hospital. The patient remained in the asystole state. A total of 8A of adrenaline was used every three minutes, and cardiopulmonary resuscitation was performed, but waveforms did not change. There was no return of spontaneous circulation. At 19:39, the patient was confirmed dead. Postmortem diagnostic imaging was performed by CT. There were no obvious causes in the head or thoracoabdominal region. Blood sampling failed to identify the cause of death, and as a result of autopsy by the police, it was determined that there was no extrinsic factor, and the cause of death was determined as intrinsic cardiac death. There was a possibility of thrombosis or myocardial infarction due to high D-dimer levels. The outcome of poriomania and traumatic injury on the head and right lower leg was unknown. The outcome of asystole, possibility of thrombosis, and possibility of myocardial infarction was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: The causality with this vaccine cannot be ruled out. The possibility of thrombosis or myocardial infarction from high D-dimer levels and other factors and the influence of diabetes mellitus from hyperglycaemia are considered. The relationship between cause of death and adverse events is unknown. Follow-up received on 17-MAR-2022 Updated: Patient Information, Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments .Company Comment: Although the event of thrombosis and myocardial infarction developed after the administration of ELASOMERAN, preexisting conditions are also considered to have affected the event.
[redacted]		This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] [redacted]on 24-Feb-2022. The most recent information was received on 27-Mar-2022 and was forwarded to Moderna on 04-Apr-2022. .This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref[redacted]. On 27-Mar-2022, follow-up information, reported by a physician, was received by Takeda via Moderna's adverse reaction reporting site[redacted]. On 28-Mar-2022, follow-up information, reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref[redacted]. On 16-Jun-2021, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 07-Jul-2021, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, body temperature before the vaccination: 36.1 degrees Celsius. On 07-Feb-2022, at 16:30, the patient received the 3rd vaccination with this vaccine. On 08-Feb-2022, at 08:00, myocarditis developed. The patient had shortness of breath and difficulty moving the body. On 09-Feb-2022, the patient visited an outpatient department. Blood pressure was 112/62 with body temperature of 37.0 degrees Celsius, SpO2 of 96% (RA). Blood tests revealed elevations in CK 9,572 U/L, CK-MB 78.5 U/L, troponin T 0.1 ng/mL, CRP 7.16 mg/dL, and D-dimer 3.2 mcg/mL. Electrocardiogram showed flat T waves in V4-6. The patient was hospitalized. On 12-Feb-2022, worsening of respiratory status was noted. Shortness of breath and polypnea were observed. Electrocardiogram showed ST depressions in V2-6, negative T waves, which were findings of myocarditis. Echocardiography showed left ventricular ejection fraction of 30%, local or diffuse dysfunction in the right or left ventricle, and decreased contraction of the anterior wall. The patient went into a shock state. The patient had no response to diuretic, vasopressor, and cardiac stimulant. At 15:44, the patient died. The outcome of myocarditis and shock state was reported as fatal. No follow-up investigation will be made. Follow-up received on 27-MAR-2022 Updated: Other Relevant History, Lab Data, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
[redacted]		This case was initially received via European Medicines Agency (Reference number: [redacted] [redacted]) on 25-Feb-2022. The most recent information was received on 17-Mar-2022 and was forwarded to Moderna on 17-Mar-2022. .This regulatory authority case was reported by an other health care professional and describes the occurrence of OFF LABEL USE (dose 1 and 2 comirnaty, dose 3 Moderna), INTERCHANGE OF VACCINE PRODUCTS (Moderna vaccine during autumn 2021) and DEATH (died on 18Jan2022) in a 95-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 016G21A) for COVID-19 immunisation. . .Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 immunisation.. .No Medical History information was reported.. .On 04-Jun-2021, the patient received first dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form..On 21-Jul-2021, received second

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		dose of TOZINAMERAN (COMIRNATY) (unknown route) dosage was changed to 1 dosage form..On 28-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 28-Dec-2021, the patient experienced OFF LABEL USE (dose 1 and 2 comirnaty, dose 3 Moderna) (seriousness criteria death and medically significant). 28-Dec-2021, the patient experienced INTERCHANGE OF VACCINE PRODUCTS (Moderna vaccine during autumn 2021) (seriousness criteria death and medically significant). The patient died on 18-Jan-2022. The cause of death was not reported. It is unknown if an autopsy was performed. . . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .No concomitant medications were provided..Dosage text for suspect product Spikevax was reported as DOSE 3 (BOOSTER), SINGLE and for co-suspect product Dosage text was reported as DOSE 1, SINGLE and DOSE 2, SINGLE..No treatment medication was reported...Company comment: This regulatory case concerns a 95-year-old, female patient with history of interchange of vaccine products (two doses of Pfizer BioNTech covid19 vaccine), who experienced unexpected fatal event of Death approximately 7 months after receiving third dose (booster) of mRNA-1273 vaccine. Interchange of vaccine products and Off label use are also reported in the case with a fatal outcome. It is unknown if an autopsy was done, and the cause of death was reported as unknown. Advanced age of the patient could be a risk factor. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events seriousness assessed as per Regulatory Authority reporting.. .This case was linked to [redacted] [redacted](E2B Linked Report).. .Most recent FOLLOW-UP information incorporated above includes:.On 17-Mar-2022: Significant Follow Up: Spikevax start date and batch number updated, Comirnaty start date of two doses updated. Interchange of vaccine products and off label use start date was updated as 28-Dec-2021. Narrative updated.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] [redacted] on 25-Feb-2022 and was forwarded to Moderna on 25-Feb-2022. .This regulatory authority case was reported by a physician and describes the occurrence of DEATH (fatalities) in a 65-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 091F21A) for COVID-19 vaccination. . .Previously administered products included for Product used for unknown indication: COMIRNATY (Dose 1: Adult Comirnaty-30 Pfizer Vaccine, 10/05/2021, Left Arm, Intramuscular Injection, Lot number: FA5831) on 10-May-2021, COMIRNATY (Dose 2: Adult Pfizer Comirnaty-30 Vaccine, 18/06/2021, Right Arm, Intramuscular Injection and Lot number: FD0168) on 18-Jun-2021..Past adverse reactions to the above products included No adverse event with COMIRNATY and COMIRNATY..Concurrent medical conditions included Hypertension arterial, Benign prostatic hyperplasia and Osteoarthritis generalised..Concomitant products included TOZINAMERAN (COMIRNATY) from 10-May-2021 to an unknown date for COVID-19 vaccination.. ..On 11-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. Death occurred on 12-Jan-2022 It is unknown if an autopsy was performed. . . .For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.. .Dose number for Spikevax was reported as R1...No treatment information was provided...Company comment: .This regulatory authority case concerns a 65-year-old male patient with relevant medical history of Hypertension arterial, who died (serious unexpected event of Death) one day after the administration of the mRNA-1273 vaccine (as booster vaccination, since the patient previously had received two doses of the Tozinameran COVID-19 vaccine). The cause of death remained unknown and there was no any information regarding autopsy results (if it was performed). Limited information precludes a meaningful medical assessment at this point. The rechallenge is not applicable having in mind that the patient died. The underlying medical history of Hypertension arterial remains a confounder for the reported event. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting. Having in mind that this patient received Tozinameran COVID-19 vaccine prior to vaccination with the company product, Interchange of vaccine products should have been considered in this specific case.
[redacted]		This case was initially received via European Medicines Agency (Reference number: [redacted] [redacted] on 25-Feb-2022. The most recent information was received on 24-Mar-2022 and was forwarded to Moderna on 24-Mar-2022. .This regulatory authority case was reported by a consumer and describes the occurrence of ASTHENIA (Loss of strength, arm (s) first, then body), COUGH (Cough (flu symptoms?)), NASOPHARYNGITIS (Have a cold(flu symptoms?)) and PERIPHERAL COLDNESS (ice-cold hands) in a 72-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. . .The patient's past medical history included Pneumonia (He also had pneumonia exactly 3 years ago. That's when that prednisone cure helped him on top of it. After that previous pneumonia, his lungs were completely checked and I was anxious that a spot would be found on his lungs, but they were clean!! He's recovered from that pneumonia and no longer bothered it.) in January 2019, Abdominal aneurysm in 2019 and Renal cancer (He had pneumonia 3 years ago and completely recovered from

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		prednisone treatment. Then his lungs were checked and were clean but there was a spot (cancer) on his kidney. The tumour was in his kidney and was removed about 2.5 years ago, received 'free letter' after examination pathologist and again came out of the top fit, did not need a chemo cure (rinsing in the beginning).) in 2019..Previously administered products included for Product used for unknown indication: BioNTech/Pfizer vaccine (Comirnaty) COVID-19 VACCINE PFIZER SUSPENSION FOR INJECTION 0.3 ML on 31-May-2021 and BioNTech/Pfizer vaccine (Comirnaty) COVID-19 VACCINE PFIZER SUSPENSION FOR INJECTION 0.3 ML on 15-Jul-2021..Past adverse reactions to the above products included Injection site pain with BioNTech/Pfizer vaccine (Comirnaty) COVID-19 VACCINE PFIZER SUSPENSION FOR INJECTION 0.3 ML and BioNTech/Pfizer vaccine (Comirnaty) COVID-19 VACCINE PFIZER SUSPENSION FOR INJECTION 0.3 ML..Concurrent medical conditions included Smoker (I don't have any numbers. My dad smoked. Even when he was here, he went outside regularly.) and COPD.. ..On 03-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 09-Jan-2022, the patient experienced ASTHENIA (Loss of strength, arm (s) first, then body) (seriousness criteria death and life threatening). On 10-Jan-2022, the patient experienced VOMITING (vomiting, productive in the beginning, later more prone to vomit, walked around with a bucket, but bucket remained empty.), MYALGIA (Muscle Pain), NAUSEA (nausea) and MALAISE (Don't feel good). On 17-Jan-2022, the patient experienced CHILLS (Cold shivers) and PERIPHERAL COLDNESS (ice-cold hands) (seriousness criteria death and life threatening). On 20-Jan-2022, the patient experienced COUGH (Cough (flu symptoms?)) (seriousness criteria death and life threatening) and NASOPHARYNGITIS (Have a cold(flu symptoms?)) (seriousness criteria death and life threatening). On 22-Jan-2022, the patient experienced INSOMNIA (Haven't slept in 72 hours. I still thought that was strange, I said to my father "if you feel sick or bad, then you would prefer to sleep, wouldn't you?", but he couldn't do that. Or very restless.). The patient died on 25-Jan-2022. The reported cause of death was copd. It is unknown if an autopsy was performed. At the time of death, INSOMNIA (Haven't slept in 72 hours. I still thought that was strange, I said to my father "if you feel sick or bad, then you would prefer to sleep, wouldn't you?", but he couldn't do that. Or very restless.) had not resolved and VOMITING (vomiting, productive in the beginning, later more prone to vomit, walked around with a bucket, but bucket remained empty.), CHILLS (Cold shivers), MYALGIA (Muscle Pain), NAUSEA (nausea) and MALAISE (Don't feel good) outcome was unknown. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.In December 2019, Physical examination: not alarming Measurement aneurysm: the measurement was not alarming, actually not to worry about but came back after half a year to see if there was any growth..In June 2020, Physical examination: no need for concern Aneurysm measurement: The second measurement was about half a year later. When it turned out that no growth had been detected, there was no need for concern, a half-yearly measurement was not necessary...On 17-Jan-2021, SARS-CoV-2 test: negative (Negative) negatively.. . . . .Concomitant medications were not reported ..Treatment information was not provided...Company Comment: This is a regulatory, fatal case concerning a 72-year-old male patient with reported medical history of COPD, Smoker, Abdominal aneurysm, Renal cancer, and previous COVID-19 Vaccination history with BioNTech/Pfizer vaccine (Comirnaty), who experienced the unexpected serious events of Nasopharyngitis, Cough, Peripheral Coldness and Asthenia. The events were life-threatening and led to the eventual demise of the patient as reported by the regulatory authority. The event Asthenia 6 days after receiving a dose (3rd dose of the COVID-19 Vaccination) of mRNA-1273 Vaccine. Peripheral Coldness occurred 14 days later while Cough and Nasopharyngitis occurred 17 days later. The patient died approximately 22 days after a dose of mRNA-1273 vaccine was received. It is unknown if autopsy was performed. The reported cause of death was COPD. The medical history of COPD, Smoker, Abdominal aneurysm, and Renal cancer remains a confounder. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 24-Mar-2022: Significant follow up appended: Relevant medical history details updated, Event and lab test added..On 24-Mar-2022: Translation received on 29-MAR-2022 contains translated event verbatim with no new information.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 23-Feb-2022 and was forwarded to Moderna on 23-Feb-2022. .This regulatory authority case was reported by a physician and describes the occurrence of RESPIRATORY ACIDOSIS (respiratory acidosis) and CEREBROVASCULAR ACCIDENT (Patient has become suddenly reduced admissible 1 day after booster vaccination, presumably due to cerebral cause such as cerebral hemorrhage/infarction) in an 82-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 216036) for COVID-19 vaccination. . .The patient's past medical history included Resuscitation (2011 abdominal aortic aneurysm wv tubular prosthesis, hereby resuscitation) in 2011, Abdominal aortic aneurysm in 2011, Ex-smoker in 1973, Coronary artery bypass graft in 2019, Percutaneous

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		coronary intervention (2007 PTCA ramus descendens anterior) in 2007 and Aortic aneurysm repair (bioprosthesis) in 2011..Previously administered products included for Product used for unknown indication: COMIRNATY on 24-Mar-2021, BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST on 01-Jun-2021, BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST on 01-Jun-2021, BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST on 01-Jun-2021..Past adverse reactions to the above products included Balance difficulty with BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST; Dizziness with BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST; Dyspnoea with BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST; and No adverse reaction with COMIRNATY..Concurrent medical conditions included Hypertension, Atrial fibrillation (arrhythmias-atrial fibrillation. due to high risk of bleeding, no oral anticoagulation started, only acetylsalicylic acid), Implantable defibrillator user (not mentioned by reporter, but described in autopsy journal), Wheelchair user, Penicillin allergy and Plasmacytoma (From history as noted in autopsy report: Isolated plasmacytoma Th5/Th6. No Kahler at follow-up)..Concomitant products included METOPROLOL TARTRATE (METOPROLOL-BC), SALBUTAMOL (SALBUTAMOL A), TIOTROPIUM and ACETYLSALICYLZUUR for an unknown indication.. ..On 30-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 31-Dec-2021, the patient experienced RESPIRATORY ACIDOSIS (respiratory acidosis) (seriousness criterion death) and CEREBROVASCULAR ACCIDENT (Patient has become suddenly reduced admissible 1 day after booster vaccination, presumably due to cerebral cause such as cerebral hemorrhage/infarction) (seriousness criterion death). The patient died on 02-Jan-2022. The reported cause of death was respiratory acidosis suspected in cerebral hypoventilation (skull obduction follows) and hypoventilation by cerebral cause. An autopsy was performed. The autopsy-determined cause of death was no abnormalities seen to organs. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 03-Jan-2021, Autopsy: no particularities ABDOMEN: The liver weighs 1086 g. No particularities at cut. The spleen weighs 182 g. No specifics at cut. Due to the presence of a trouser prosthesis in the abdominal aorta. Both kidneys weigh 300 g. No specifics at cut. Gastrointestinal tract and pancreas: no particularities. Bladder and prostate: no particularities., no abnormalities externally BRAIN: A skull production was performed. The brain weigh 1680 g. No abnormalities externally. These will be investigated in university center, hypereosinophilia and contraction band necrosis MICROSCOPY: Bone marrow: reactive changes. Adrenal glands: no specifics. Liver and spleen: low centrilobular congestion of the liver. Slight expansion of the red pulp. No splenitis. Pancreas: Advanced Autolysis. Left kidney: no specifics. Right kidney: no specifics. Left lung: no details. Right lung no specifics. Myocardial: picture of chronic ischemic cardiomyopathy. Under the form of multiple spotted old fibrous fireplaces. Microscopically no features of recent ischemia. Local some hypereosinophilia and contraction band necrosis. However, no infiltration of inflammation cells. There was extensive sampled. and no particularities. The left lung weighs 333 g, the right lung 372 g. No specifics at cut. No embolisms. The heart shows extensive adhesions to previous coronary surgery where it is technically impossible to properly assess the internal status of the coronaries. Presence of a pacemaker. The aortic thoracic aorta exhibits moderately pronounced atherosclerosis. However, the carotid arteries are easily accessible. The left ventricular wall has a thickness of 3 cm with image matching a concentric left ventricular hypertrophy. In the LDH test, there is a fairly pronounced decolouration of the left ventricular wall. Recent ischemia? Infrared? Agonal? Throat skeleton, trachea, esophagus and thyroid: no particularities...In January 2021, Autopsy: obduction has occurred Obduction has occurred, in which the organs were not diagnosed with any pathology that could explain death...In December 2021, SARS-CoV-2 test: negative (Negative) negative..On 31-Dec-2021, Laboratory test: no notable abnormalities (Inconclusive) platelet 130x10^9 (platelets have been slightly lowered since 2019), CRP 14, pH 7.24, pCO2 94, bicarbonate 30.5, Po2 111, coagulation values have not been determined. No notable abnormalities.. . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .No treatment information were given...Company comment:.This is a regulatory authority case concerning a 82-year-old, male patient with relevant medical history of hypertension, abdominal aortic aneurysm in 2011, resuscitation (2011, abdominal aortic aneurysm with tubular prosthesis, hereby resuscitation), aortic aneurysm repair (2011, bioprosthesis) atrial fibrillation (due to high risk of bleeding, no oral anticoagulation started, only acetylsalicylic acid), coronary artery bypass graft in 2019, implantable defibrillator user, percutaneous coronary intervention (2007 PTCA ramus descendens anterior), wheelchair user, former smoker in 1973 and Plasmacytoma and with vaccine history of receiving 2 doses of another brand of

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		Covid-19 vaccine (Covid-19 vaccine Comirnaty) as previous doses, who experienced the unexpected serious (fatal according to regulatory authority) AESI event of presumably cerebrovascular accident and unexpected serious (fatal according to regulatory authority) event of respiratory acidosis. The events occurred approximately 1 day after the unknown dose number of mRNA-1273 vaccine administration. The reported cause of death was respiratory acidosis suspected in cerebral hypoventilation (skull obduction follows) and hypoventilation by cerebral cause. An autopsy was performed with autopsy findings of, obduction has occurred, in which the organs were not diagnosed with any pathology that could explain death. The autopsy-determined cause of death was no abnormalities seen to organs. The reported medical history remains confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
[redacted]		This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 25-Feb-2022. The most recent information was received on 09-Mar-2022 and was forwarded to Moderna on 16-Mar-2022. . This case was reported by a physician via the Drug Information Center. On 09-Mar-2022, follow-up information, reported by a physician, was received by Takeda via Moderna's adverse reaction reporting site ([redacted], and reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, [redacted]. On 13-Jun-2021, at 11:00, the patient received the 1st dose of coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 04-Jul-2021, at 11:00, the patient received the 2nd dose of coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, body temperature before the vaccination: 35.8 degrees Celsius. On 23-Feb-2022, around 10:00, the patient received the 3rd vaccination with this vaccine. After vaccination, the patient experienced mild headache but walked back to the room alone and ingested meals. At 17:45, the patient fell and lost consciousness in cardio-respiratory arrest. After confirming that the patient was unconscious, cardiopulmonary resuscitation was started. As an ambulance call was made, intravenous injection of adrenaline was performed since electrocardiogram showed cardiac arrest. The waveform then became pulseless electrical activity, but spontaneous circulation was not returned. At 18:57, the patient was confirmed dead in a hospital where the patient was transported. Diagnostic imaging at the time of death was performed. There were findings of aortic dissection. Pleural effusion and blood were mixed in the aorta. The outcome of headache, fall, and loss of consciousness was unknown. The outcome of cardio-respiratory arrest and aortic dissection was reported as fatal. No follow-up investigation will be made. Follow-up received on 09-MAR-2022 Updated: Reporter Information, Patient Information, Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 28-Feb-2022 and was forwarded to Moderna on 28-Feb-2022. .This regulatory authority case was reported by a physician and describes the occurrence of MENINGITIS (Meningitis) and MULTIPLE ORGAN DYSFUNCTION SYNDROME (Multiple organ failure) in a 69-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. . .Date of death not given. First result of the autopsy with proof unspec. Coatings on the meninges in the sense of meningitis. .Previously administered products included for COVID-19 vaccination: COMIRNATY and COVID-19 VACCINE ASTRAZENECA (Vaxzevria)..Past adverse reactions to the above products included No adverse event with COMIRNATY and COVID-19 VACCINE ASTRAZENECA.. ..On 16-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 16-Jan-2022, the patient experienced MENINGITIS (Meningitis) (seriousness criteria death, hospitalization and life threatening) and MULTIPLE ORGAN DYSFUNCTION SYNDROME (Multiple organ failure) (seriousness criteria death, hospitalization and life threatening). The reported cause of death was Multiple organ failure. An autopsy was performed. The autopsy-determined cause of death was Meningitis. . . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .Concomitant medications were not provided...Treatment information was not provided...Company comment: This is a regulatory case concerning a 69 year-old, male patient with no reported medical history, who experienced the fatal serious unexpected, events of meningitis (AESI) and Multiple organ dysfunction syndrome, the same day after the mRNA-1273 vaccine, received as the booster dose of the COVID-19 vaccination schedule. Patient's death date was not provided but the duration of both events was reported as 2 days. The autopsy determined cause of death was meningitis and an additional cause of death reported in the case was Multiple organ dysfunction syndrome. Additionally, Interchange of vaccine products was noted in the case, vaccination with a dose of COVID-19 vaccine Tozinameran and a dose of NRVV AD (CHADOX1 NCOV-19) no dates provided. No further clinical information was available for medical review. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.

Case ID	WW Identifier	Narrative Complete
[redacted]	[redacted]	This case was received via European Medicines Agency (Reference number [redacted] on 01-Mar-2022 and was forwarded to Moderna on 01-Mar-2022. .This regulatory authority case was reported by a physician and describes the occurrence of PULMONARY EMBOLISM (Pulmonary embolism) and DEATH (Found dead (cause undetermined)) in a 64-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000137A) for COVID-19 vaccination. . .Previously administered products included for COVID-19 vaccination: Comirnaty BNT162b2 on 28-Apr-2021 and Comirnaty BNT162b2 on 09-Jun-2021..Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Comirnaty BNT162b2.. ..On 02-Feb-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 09-Feb-2022, the patient experienced PULMONARY EMBOLISM (Pulmonary embolism) (seriousness criterion death) and DEATH (Found dead (cause undetermined)) (seriousness criterion death). The patient died on 09-Feb-2022. The cause of death was not reported. It is unknown if an autopsy was performed. . . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .Concomitant medications were not provided..Treatment information was not provided..Patient found dead, no concomitant diseases in history. .Dosage text was reported as booster vaccination..Company comment:.This regulatory authority case concerns a 64 year old male patient with an interchange of vaccine products (Comirnaty) and no reported medical history who experienced the unexpected serious (seriousness criterion-death) events of Pulmonary embolism(AESI) and Death, 7 days after receiving the third dose with mRNA-1273 vaccine. The events had a fatal outcome with death occurring on the 8th day of vaccine administration. The cause of death was reported as unknown. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness retained as per Regulatory Authority reporting.
[redacted]	[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 01-Mar-2022 and was forwarded to Moderna on 01-Mar-2022. .This regulatory authority case was reported by a physician and describes the occurrence of CARDIAC ARREST (Arrest cardiac) and DEATH (Found dead (cause undetermined)) in a 61-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000136A) for COVID-19 vaccination. . .The patient's past medical history included Arterial hypertension..Previously administered products included for COVID-19 vaccination: COVID-19 VACCINE ASTRAZENECA on 14-May-2021 and Comirnaty BNT162b2 on 23-Jul-2021..Past adverse reactions to the above products included No adverse event with COVID-19 VACCINE ASTRAZENECA and Comirnaty BNT162b2.. ..On 18-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 30-Dec-2021, the patient experienced CARDIAC ARREST (Arrest cardiac) (seriousness criterion death) and DEATH (Found dead (cause undetermined)) (seriousness criterion death). The patient died on 30-Dec-2021. The cause of death was not reported. An autopsy was not performed. . . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .No concomitant medication use was provided..No treatment medication was provided...Company Comment: This regulatory authority case concerns a 61 year old male patient with relevant medical history of hypertension, vaccinated with two different covid 19 vaccine for primary series vaccine 1st dose was covid 19 vaccine Astra Zeneca , 2nd dose Covid 19 vaccine Pfizer (both vaccines given with no reported adverse events), who experienced Serious (fatal) unexpected events of Cardiac arrest and Death which occurred 12 days post vaccination with the 3rd dose of mRNA-1273 vaccine . The details surrounding the death of this patient was not reported . The cause of death was reported as unknown and no autopsy was done. The history of hypertension of this patient and the history of vaccination with the two other Covid 19 vaccine namely the Covid 19 Vacccine Astra Zeneca and the Covid 19 vaccine Pfizer are considered as confounders for the events. The benefit -risk relationship of mRNA -1273 (Moderna Covid 19 Vaccine) is not affected by this report. As mentioned above this patient received Covid 19 vaccine astra Zeneca as first dose , Covid 19 vaccine Pfizer as 2nd dose and the mRNA-1273 vaccine as third dose hence event of Inappropriate Schedule of Product administration occurred.
[redacted]	[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 01-Mar-2022 and was forwarded to Moderna on 01-Mar-2022. .This regulatory authority case was reported by a consumer and describes the occurrence of CEREBROVASCULAR ACCIDENT (tired and listless) in a 67-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004951) for COVID-19 vaccination. . .Patient had current conditions of mild asthma,type 2 diabetes..On 05-MAR-2016 a small stroke without permanent damage. .The patient's past medical history included Apoplectic fit in 2016..Previously administered products included for Prophylactic vaccination: COVID-19 Vaccine Janssen Injektionssuspension COVID-19 Vaccine JanssenCOVID-19-Impfstoff Ad26.COV2-S on 16-Jun-2021..Past adverse reactions to the above products included No adverse event with COVID-19 Vaccine Janssen Injektionssuspension COVID-19 Vaccine JanssenCOVID-19-Impfstoff Ad26.COV2-S.. ..On 01-Dec-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 02-Dec-2021, the patient experienced

Case ID	WW Identifier	Narrative Complete
		CEREBROVASCULAR ACCIDENT (tired and listless) (seriousness criterion death). The patient died on 09-Dec-2021. The reported cause of death was Apoplectic fit. It is unknown if an autopsy was performed. . . . . .Concomitant medications were not reported...It was reported that person was alone and felt unwell and weak one day after the vaccination and lay down around noon..Patient was diagnosed in the night with severe stroke. Patient was in coma for a week and died on 09Dec2021...Treatment medications were not reported...Company Comment: This regulatory case concerns a 67-year-old, male patient with relevant medical history of Stroke (Apoplectic fit) without permanent damage (2016) and Type 2 Diabetes Mellitus (T2DM), and past drug history of administration of a dose of the Janssen COVID-19 vaccine, who experienced the unexpected, serious (fatal) AESI of cerebrovascular accident. The event occurred 1 day after administration of the second dose of the Moderna mRNA-1273 vaccine. The patient felt unwell and weak, and lay down around noon. On the same evening, the patient did not answer calls and did not answer when the doorbell rang. He was brought to the clinic and was diagnosed with 'severe stroke'. Laboratory test/s and treatment information were not provided. The report stated that the patient was in a coma for a week and expired on 09Dec2021 (8 days after vaccination). It is unknown if an autopsy was performed. However, the reported cause of death was 'Apoplectic fit'. The patient's medical history of Stroke (Apoplectic fit) and T2DM, and past drug history of administration of a dose of the Janssen COVID-19 vaccine remain as confounders. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 03-Mar-2022 and was forwarded to Moderna on 03-Mar-2022. .This regulatory authority case was reported by a physician (subsequently medically confirmed) and describes the occurrence of DEATH (Found dead (cause undetermined)) in a 60-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 045G21A) for COVID-19 vaccination. . .Previously administered products included for COVID-19 vaccination: COMIRNATY (Comirnaty BNT162b2) on 12-May-2021 and COMIRNATY (Comirnaty BNT162b2) on 18-Jun-2021..Past adverse reactions to the above products included No adverse event with COMIRNATY and COMIRNATY.. ..On 14-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. Death occurred on 06-Feb-2022 The patient died on 06-Feb-2022. The cause of death was not reported. It is unknown if an autopsy was performed. . . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .No Concomitant medications were reported...Treatment information was not provided...This is a regulatory case concerning a 60-year-old male patient with no details on past medical history, who presented with the unexpected event of death. Previously administered product is the Cominarty Covid-19 vaccine. The event occurred approximately 23 days after the received dose of mRNA - 1273 vaccine. The patient was reportedly found dead and the cause of death was not reported. It is also unknown if and autopsy was performed. The reporter did not provide any causality assessment. The benefit risk relationship of vaccine is not affected by this report
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 03-Mar-2022 and was forwarded to Moderna on 03-Mar-2022. .This regulatory authority case was reported by a physician and describes the occurrence of PYREXIA (Fever), HYPOXIA (Hypoxia) and DYSPNOEA (Dyspnea) in an 83-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 017G21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. . .The patient's past medical history included Coagulation disorder, Stroke in 2021, Transient ischaemic attack in 2019, Thyroidectomy total in 2019 and Transfusion in December 2021..Previously administered products included for COVID-19 immunisation: Comirnaty from 09-Mar-2021 to 06-Apr-2021..Past adverse reactions to the above products included No adverse event with Comirnaty..Concurrent medical conditions included Lymphoma (medullary lymphoma).. ..On 26-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .5 dosage form. On 26-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine). On 29-Jan-2022, the patient experienced PYREXIA (Fever) (seriousness criterion death). On 30-Jan-2022, the patient experienced HYPOXIA (Hypoxia) (seriousness criteria death and medically significant) and DYSPNOEA (Dyspnea) (seriousness criterion death). On 26-Jan-2022, COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) had resolved. The patient died on 30-Jan-2022. The reported cause of death was Transfusion, Chemotherapy, Fever, COVID-19 immunisation and medullary lymphoma. An autopsy was not performed. . . .For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.. .No concomitant medications were reported...Dosage text given as R1...Company Comment:.This is an RA case concerning a -83year-old, female patient with a history of medullary lymphoma, coagulation disorder, total thyroidectomy (2019), TIA (2019), stroke (2021) and transfusion in Dec/2021. After completing primary vaccination with Pfizer vaccine in April 2021, patient received the third dose of

Case ID	WW Identifier	Narrative Complete
		mRNA1273 on 22JAN2022 and 3 days later starts presenting fever. The day after she experienced dyspnea with hypoxia. All the events were reported as fatal and causes of death were transfusion, chemotherapy, lymphoma, COVID-19 vaccination and fever. Date of death was not reported. Patient's medical history is a cofounder as not only she had several comorbidities which lead to a frail state, but also it appears that the Lymphoma was still ongoing and being treated with chemotherapy. Cancer and chemotherapy are immunosupressors potentializing the frail state and increasing the risk of death due to other causes. Event seriousness captured according RA assessment...No treatment medications were reported...Reporter mentioned Causality as Method of assessment includes FRENCH IMPUTABILITY METHOD and Result of Assessment includes C2 S1 (I1 dubious) B2.
[redacted]		This regulatory authority case was reported by an other health care professional and describes the occurrence of GUN SHOT WOUND (Gun shot wound) in a 65-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 061621A) for an unknown indication. . .Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for an unknown indication.. .No Medical History information was reported.. .On an unknown date, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form and dose of TOZINAMERAN (COMIRNATY) (Intramuscular) 1 dosage form..On an unknown date, received dose of TOZINAMERAN (COMIRNATY) (Intramuscular) dosage was changed to 1 dosage form. On 30-Jan-2022, the patient experienced GUN SHOT WOUND (Gun shot wound) (seriousness criterion death). It is unknown if an autopsy was performed. . . .For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments.. .No relevant concomitant medications were reported. ATC code for Tozinameran and Elasomeran were J07BX. Vaccine was administered on 20 Aug 2021 and 10 Sep 2021. No treatment information was provided...Company comment: This is a regulatory case concerning a 65-year-old male patient with no reported medical history, who experienced the fatal event gun shot wound, more than 4 months after receiving dose of mRNA-1273. Death date and cause of death were not reported. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 is not affected by this report.
[redacted]		This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 03-Mar-2022. The most recent information was received on 29-Mar-2022 and was forwarded to Moderna on 06-Apr-2022. .This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, [redacted]. On 19-Mar-2022, follow-up information, reported to Takeda by a physician, was received via the Moderna's adverse reaction reporting site [redacted] On 29-Mar-2022, follow-up information was received from a physician. On 22-Jun-2021, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 13-Jul-2021, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 19-Feb-2022, the patient received a regular exam. The patient's condition was stable. On an unknown date, body temperature before the vaccination: 36.2 degrees Celsius. On 26-Feb-2022, around 11:10, the patient received the 3rd vaccination with this vaccine. The patient returned home without any particular problems. Around 27-Feb-2022, the patient died suddenly. On 01-Mar-2022, in the morning, the patient was found lying dead on the hallway at home. On an unknown date, after postmortem inspection, it was determined that the patient died of natural causes and that she died between 27-Feb-2022 and the morning of 28-Feb-2022. No necropsy was performed. The cause of death was cardiac valvulopathy. The outcome of cardiac valvulopathy was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: Although sudden death may occur naturally considering that the patient was at an old age with underlying diseases, it is likely that the patient died on the next day of the vaccination, and the causality to this vaccine cannot be ruled out. The patient originally lived alone, and the patients condition since returning home after the vaccination is unknown. Other possible causes include advanced age, cardiac valvulopathy, and cerebrovascular disorder. Since the patient died on the next day or two days after administration of the vaccine, the occurrence of the adverse event is temporally related to the timing of administration of the vaccine. Some drugs were started on 19-Feb-2022, but there were no particular problems for a week, so the occurrence of the adverse event is not related to concomitant drugs. Since there is no information on symptoms leading to the death, the relationship between the occurrence of adverse events and pathological factors of underlying diseases and complications is unknown. There is no relationship between the cause of death and the adverse event. Since the patient died on the next day or two days after vaccination with this vaccine, it is considered that an adverse event cannot be ruled out. Follow-up received on 19-MAR-2022 Updated: Patient Information, Other Relevant History, Narrative Follow-up received on 29-MAR-2022 Updated: Patient Information, Other Relevant History, Product Information, Event Information, Narrative, Reporter Comments Company Comment:

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		Sudden death can be also considered as an accidental disease although it developed after the administration of ELASOMERAN.
[redacted]		This case was initially received via European Medicines Agency (Reference number: [redacted] on 04-Mar-2022. The most recent information was received on 11-Mar-2022 and was forwarded to Moderna on 11-Mar-2022. .This regulatory authority case was reported by a consumer and describes the occurrence of CEREBRAL HAEMORRHAGE (Deaths after cerebral hemorrhage) in a 49-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214008) for COVID-19 vaccination. . .The patient's past medical history included Depression..Previously administered products included for Prophylactic vaccination: Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant])COVID-19 Vaccine AstraZeneca suspension for injectionCOVID-19 Vaccine AstraZeneca on 26-Apr-2021 and Comirnaty BNT162b2 on 19-Jul-2021..Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant])COVID-19 Vaccine AstraZeneca suspension for injectionCOVID-19 Vaccine AstraZeneca..Concurrent medical conditions included Cannabis use and Asthma bronchial.. ..On 21-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 09-Feb-2022, the patient experienced CEREBRAL HAEMORRHAGE (Deaths after cerebral hemorrhage) (seriousness criterion death). The patient died on 15-Feb-2022. The reported cause of death was Cerebral haemorrhage. It is unknown if an autopsy was performed. . . . .Concomitant medication was not reported...Reported massive brain hemorrhage...Treatment information was not reported....Company comment: This regulatory authority case concerns a 49 year old male patient with an interchange of vaccine products (Vaxzevria COVID-19 vaccine and Comirnaty) and relevant medical history of cannabis use, who experienced the unexpected serious (seriousness criterion-death) AESI of Cerebral haemorrhage, about 50 days after receiving the third dose with mRNA-1273 vaccine. The event had a fatal outcome with death occurring after 5 days of vaccine administration. The reported cause of death was Cerebral haemorrhage. No further information was available regarding clinical course, management of the event and the autopsy report. The medical history of cannabis use could be a risk factor for the event. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event's seriousness retained as per Regulatory Authority reporting.. .Most recent FOLLOW-UP information incorporated above includes:.On 11-Mar-2022: Follow up received wherein medical history was updated.
[redacted]		This spontaneous case was reported by a non-health professional and describes the occurrence of APLASTIC ANAEMIA (Severe aplastic anemia/severe bone marrow atrophy (severe aplastic anemia cellularity 5%)), FEBRILE NEUTROPENIA (Febrile neutropenia with Klebsiella pneumoniae septicemia), KLEBSIELLA SEPSIS (Febrile neutropenia with Klebsiella pneumoniae septicemia), CIRCULATORY COLLAPSE (Circulatory system failure), RENAL FAILURE (Kidney failure), HEPATIC FAILURE (Liver failure), WOUND HAEMORRHAGE (While working, she had bleeding that was difficult to stop from a wounded), HAEMOPTYSIS (Coughing up blood in the morning) and DECREASED IMMUNE RESPONSIVENESS (Persistent low immunity) in a 50-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 049F21A) for COVID-19 vaccination. . .The patient had no underlying disease. .Previously administered products included for COVID-19 vaccination: Sinovac (Sinovac) on 08-Apr-2021, Sinovac (Sinovac) on 06-May-2021 and Pfizer (Pfizer) on 09-Aug-2021..Past adverse reactions to the above products included No adverse reaction with Pfizer, Sinovac and Sinovac.. ..On 27-Dec-2021, the patient received fourth dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On 28-Dec-2021, the patient experienced APLASTIC ANAEMIA (Severe aplastic anemia/severe bone marrow atrophy (severe aplastic anemia cellularity 5%)) (seriousness criteria death, hospitalization and medically significant). On an unknown date, the patient experienced FEBRILE NEUTROPENIA (Febrile neutropenia with Klebsiella pneumoniae septicemia) (seriousness criteria death, hospitalization and medically significant), KLEBSIELLA SEPSIS (Febrile neutropenia with Klebsiella pneumoniae septicemia) (seriousness criteria death, hospitalization and medically significant), CIRCULATORY COLLAPSE (Circulatory system failure) (seriousness criteria death, hospitalization and medically significant), RENAL FAILURE (Kidney failure) (seriousness criteria death, hospitalization and medically significant), HEPATIC FAILURE (Liver failure) (seriousness criteria death, hospitalization and medically significant), WOUND HAEMORRHAGE (While working, she had bleeding that was difficult to stop from a wounded) (seriousness criteria death and hospitalization), HAEMOPTYSIS (Coughing up blood in the morning) (seriousness criteria death and hospitalization) and DECREASED IMMUNE RESPONSIVENESS (Persistent low immunity) (seriousness criterion medically significant). The patient was hospitalized for 60 days due to APLASTIC ANAEMIA, CIRCULATORY COLLAPSE, FEBRILE NEUTROPENIA, HAEMOPTYSIS, HEPATIC FAILURE, KLEBSIELLA SEPSIS, RENAL FAILURE and WOUND HAEMORRHAGE. The patient was treated with DEXAMETHASONE at a dose of High dose. The patient died on 03-Mar-

Case ID	WW Identifier	Narrative Complete
		2022. The reported cause of death was febrile neutropenia with klebsiella pneumoniae septicemia, severe aplastic anemia/severe bone marrow atrophy (severe aplastic anemia cellularity 5%), circulatory system failure, Kidney failure, Liver failure, while working, she had bleeding that was difficult to stop from a wounded, coughing up blood in the morning and febrile neutropenia with klebsiella pneumoniae septicemia. It is unknown if an autopsy was performed. At the time of death, DECREASED IMMUNE RESPONSIVENESS (Persistent low immunity) had not resolved. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 07-Sep-2021, Full blood count: normal (normal) normal..On 28-Dec-2021, Body temperature: high (High) High Fever..On an unknown date, Biopsy bone marrow: severe bone marrow atropy (abnormal) Severe Bone marrow atropy(Severe aplastic anemia, cellularity 5%)..On an unknown date, Full blood count: severe low blood count (Low) Severe Low blood count and severe low blood count Came to hospital again and Complete Blood count was checked, result: Severe low blood count..On an unknown date, Haemoglobin: 10.4 (Low) 10.4 g/dl and 9.2 (Low) 9.2 g/dl..On an unknown date, Platelet count: 3000 (Low) 3000 cells/mm3 and less than 1000 (Low) less than 1000..On an unknown date, White blood cell count: 2,170 (Low) 2,170 cell/mm3 and 2000 (Low) 2000 cell/mm3.. . .For mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown), the reporter did not provide any causality assessments.. .Concomitant product use was not provided by the reporter...The patient received Moderna vaccine as the fourth dose on 27-Dec-2021, after that she experienced fever and low platelet count. A physician diagnosed the patient with severe aplastic anemia caused by receiving the vaccine. The patient experienced persistent low immunity and severe infection...The patient had experienced headache, fever nausea, bruise on body, easy bruising without previous bumps, bruise on the body was not improving then she went to hospital. The symptoms had occurred 1 day after the fourth vaccination. She had received concentrated platelets and came back to work. Her condition was not improved then she came to the hospital again and then complete blood count was checked. She had a high fever and severe infection in the bloodstream. It had spread to circulatory system failure, kidney failure, liver failure and eventually death/passed away...Treatment for the event included treatment with the drug, the blood, and the blood product but condition was not improved, and the patient passed away on 03-Mar-2022 at 07.04 am. The vaccine recipient had received treatment for bruising. She had received concentrated platelets. She was treated with standard medication but was not responding...For the patient, the data had been collected and a joint meeting between a central post-vaccination adverse event expert panel and physicians who took care of the patient concluded that she had severe bone marrow atropy as a result, blood cells and platelets were very low. There was a potential for infection with K. pneumoniae bacteria in the bloodstream. For Acquired aplastic anemia, it could be caused by many reasons such as exposure to chemicals, radioactive substance or from the body's own immune dysfunction, cytotoxic T-cells were stimulated to destroy their own stem cells...Company comment: This case concerns a death of a 50-year-old female patient, with no medical history reported, who experienced the unexpected, serious (Hospitalization, Medically significant, Death) event of Aplastic anaemia, 01 day after and febrile neutropenia, klebsiella sepsis, circulatory collapse, hepatic failure, the events of wound haemorrhage, haemoptysis (Hospitalization, Death) and decreased immune responsiveness (Medically significant) on an unknown date after receiving the 4 dose of m RNA 1273 vaccine in the COVID-19 vaccination series. The patient was previously vaccinated with Sinovac vaccine (two doses) and the 3 dose with Pfizer vaccine about 4 months prior to the 4 dose, with no adverse reactions seen with Pfizer and Sinovac. Interchange of vaccine products was noted. As reported, after mRNA-1273 vaccination the patient experienced fever and low platelet count and a severe aplastic anemia was diagnosed. The patient experienced persistent low immunity and severe infection. On an unknown date, Biopsy bone marrow showed severe bone marrow atropy (abnormal) Severe Bone marrow atropy (Severe aplastic anemia, cellularity 5%), Severe Low blood counts(low Hb, WBC and platelets). Treatment for the event included dexamethasone at high dose, blood and the blood products but condition was not improved, and the patient passed away 2 months after Moderna vaccine administration. The reported cause of death was febrile neutropenia with klebsiella pneumoniae septicemia, severe aplastic anemia/severe bone marrow atrophy, circulatory system failure, Kidney failure, Liver failure, wound haemorrhage, and haemoptysis. At the time of death, decreased immune responsiveness had not resolved. Decreased immune responsiveness and infection were likely related to concurrent aplastic anemia. The benefit-risk relationship of mRNA-1273 is not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 07-Mar-2022: Follow-up information received contains no new info
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 07-Mar-2022 and was forwarded to Moderna on 07-Mar-2022. .This regulatory authority case was reported by a physician and describes the occurrence of RESUSCITATION (Resuscitation), BRAIN INJURY (Hypoxic brain damage), MYOCARDITIS (Myocarditis) and VENTRICULAR FIBRILLATION (Ventricular fibrillation) in a 64-year-old female patient who received mRNA-1273

Case ID	WW Identifier	Narrative Complete
		(Spikevax) for COVID-19 vaccination. . .Previously administered products included for COVID-19 vaccination: Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant])COVID-19 Vaccine AstraZeneca suspension for injectionCOVID-19 Vaccine AstraZeneca on 22-Apr-2021 and Comirnaty BNT162b2 on 02-Jun-2021..Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant])COVID-19 Vaccine AstraZeneca suspension for injectionCOVID-19 Vaccine AstraZeneca.. ..On 20-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 22-Jan-2022, the patient experienced RESUSCITATION (Resuscitation) (seriousness criteria death, hospitalization and life threatening), BRAIN INJURY (Hypoxic brain damage) (seriousness criteria death, hospitalization and life threatening), MYOCARDITIS (Myocarditis) (seriousness criteria death, hospitalization and life threatening) and VENTRICULAR FIBRILLATION (Ventricular fibrillation) (seriousness criteria death, hospitalization and life threatening). The patient died on 22-Jan-2022. The reported cause of death was 10047290. It is unknown if an autopsy was performed. . . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .No concomitant medications were reported...Treatment information was not provided..Company Comment: This regulatory case concerns a 64-year-old, female patient with no relevant medical history, who experienced the unexpected, serious (fatal, life-threatening, hospitalized) adverse events of interest Myocarditis and Ventricular fibrillation along with the unexpected, serious (fatal, life-threatening, hospitalized) event Brain injury. Resuscitation was reported as an additional event. The patient also previously received the COVID-19 vaccines of NRVV AD (CHADOX1 NCOV-19) and Tozinameran prior to the mRNA-1273 vaccine (Interchange of vaccine products). The events occurred 2 days after receiving mRNA-1273 vaccine as booster dose. Clinical course leading to demise was not provided in the case although resuscitation was performed on the patient. The patient died on the same day of the onset of events and the reported cause of death was due to ventricular fibrillation. It is unknown whether autopsy was performed. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 08-Mar-2022 and was forwarded to Moderna on 08-Mar-2022. .This regulatory authority case was reported by a physician and describes the occurrence of ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction) in a 58-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000077A) for COVID-19 vaccination. . .Previously administered products included for COVID-19 vaccination: Comirnaty BNT162b2 (Comirnaty BNT162b2) on 05-May-2021 and Comirnaty BNT162b2 (Comirnaty BNT162b2) on 23-Jun-2021..Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Comirnaty BNT162b2.. ..On 27-Jan-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, the patient experienced ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction) (seriousness criteria death and life threatening). The reported cause of death was Acute myocardial infarction. It is unknown if an autopsy was performed. . . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .Dosage text was reported as booster vaccination..Date of death not communicated. .No concomitant medication was reported..No treatment information was reported..Company comment.This regulatory authority case concerns a 58-year-old male patient, with no reported medical history, who experienced the unexpected serious fatal AESI of ACUTE MYOCARDIAL INFARCTION. On 27-Jan-2021, patient received a dose of mRNA-1273 vaccine, considered as the third dose for COVID 19 vaccination (received Comirnaty BNT162b2 as Dose 1 and 2, interchange of vaccine products). Onset date of the events was not provided; hence, latency cannot be assessed. The reported cause of death was Acute myocardial infarction. It is unknown if an autopsy was performed. Date of death was not communicated. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
[redacted]		This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 04-Mar-2022. The most recent information was received on 26-Apr-2022 and was forwarded to Moderna on 02-May-2022. .This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 04-Mar-2022. The most recent information was received on 26-Apr-2022 and was forwarded to Moderna on 02-May-2022. .This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a pharmacist, was received via the PMDA (Ref, [redacted] ..On 26-Apr-2022, follow-up information was received from a pharmacist. On an unknown date, the patient received the 1st dose of coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, the patient received the 2nd dose of coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 27-Jan-2022, in the afternoon, the patient received the 3rd vaccination with this vaccine. At night, the patient worked. On 28-Jan-2022, in the morning, the patient returned home. Thereafter, pyrexia developed. On 29-Jan-

Case ID	WW Identifier	Narrative Complete
		2022, in the morning, pyrexia resolved. The patient visited a dentist and had a wisdom tooth pulled out. At 20:06, the patient experienced syncope and incontinence and contacted the family member. Several seconds later, rolling of the eyes and loss of consciousness developed. At 20:11, the patient was found in a state of cardio-respiratory arrest. The family member initiated cardiopulmonary resuscitation. When the ambulance team contacted the patient, lethal arrhythmia and atrial fibrillation were observed. AED was activated, and DC was performed twice. At 20:43, after aspiration, a laryngeal tube was inserted into the PEA. At 20:49, the patient arrived at the reporting hospital. Bleeding from the oral cavity, bronchi, and nose was noted. The patient received resuscitation and medication, but they were ineffective. At 20:59, after heart-lung machine and circulatory assist device were attached, intensive care was started. Coronary artery angiography showed no significant stenosis. Myocardial biopsy revealed no appreciable findings. At 21:22, head CT was performed. There was no subarachnoid haemorrhage, cerebral haemorrhage, subdural haematoma, extradural haematoma, fracture, or brain oedema. No dilatations of the ventricles or sulci was found. No abnormalities were found within the orbit. The paranasal sinuses within the range of imaging were clear. There was no cerebrovascular disorder. At 21:25, pulmonary-pelvic CT was performed. The patient was diagnosed as having extensive interstitial shadows in both lungs. No thoracic or abdominal tumors were observed. Chest: No vena cava dissection, no aortic aneurysm, no intrapericardial fluid accumulation, no intrapleural fluid accumulation, and no mediastinal fluid accumulation were shown. Abnormalities in the origin of coronary vessels were unknown. No coronary vascular calcification. No pneumothorax. Slight mediastinal emphysema was found. Extensive ground-glass opacities were shown in both lungs. The opacities, which were interstitial shadows, were shown in the upper lobe and the dorsal surface of both lower lobes of the lungs and difficult to differentiate. There was no enlargement in the mediastinal, hilar, or axillary lymph nodes. Abdomen: No aortic dissection, no aortic aneurysm, and no retroperitoneal hematoma were found. There was gastric contents accumulation. No intra-abdominal fluid accumulation, no pancreatic enlargement, and no intrahepatic occupying lesions were found. No dilation was seen in the gallbladder or bile duct. No appreciable abnormalities were found in the kidneys, spleen, or adrenal glands. No enlarged lymph nodes and no thickened intestinal wall were found. Scanning images showed no obvious abnormalities in the bones of the bilateral upper extremities and proximal thigh. On 01-Feb-2022, at 05:33, the patient died. The cause of death was diagnosed as ventricular fibrillation. Autopsy was not performed because the family member did not hope it. The outcome of pyrexia was reported as resolved. The outcome of syncope, incontinence, and haemorrhage was unknown. The outcome of cardio-respiratory arrest, lethal arrhythmia, PEA, and ventricular fibrillation was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: Other lesions that could be the cause of death have not been identified. The causal relationship with this vaccination is also unknown. Follow-up received on 26-APR-2022 Updated: Patient Information, Lab Data, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
[redacted]		This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 07-Mar-2022. The most recent information was received on 20-Apr-2022 and was forwarded to Moderna on 25-Apr-2022. .This spontaneous case was reported by a physician and describes the occurrence of DEATH (Death (After the third vaccination)) in a 74-year-old female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 3005786) for COVID-19 vaccination. . .Previously administered products included for Product used for unknown indication: Comirnaty on 14-Jun-2021 and COMIRNATY on 05-Jul-2021..Past adverse reactions to the above products included No adverse event with COMIRNATY and Comirnaty.. ..On 02-Mar-2022, the patient received third dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) .25 milliliter. Death occurred on 03-Mar-2022 The patient died on 03-Mar-2022. The cause of death was not reported. It is unknown if an autopsy was performed. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 02-Mar-2022, Blood pressure measurement: 155/60 Test Result:155/60 mm[Hg]..On 02-Mar-2022, Body temperature (Unknown-37): 35.7 35.7 degree Celsius..On 02-Mar-2022, Heart rate: 84 84 per minute..On 02-Mar-2022, Oxygen saturation: 96 96 percent..On an unknown date, Blood pressure measurement: 110-120/60 mm[hg] Test Result:110-120/60 mm[Hg]..On an unknown date, Body temperature (Unknown-37): 35.7 35.7 degree Celsius.. . .For mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular), the reporter considered DEATH (Death (After the third vaccination)) to be possibly related. . .Details were unknown because the physician is not a family doctor. Adverse events before the patient's death were unknown. A disease name cannot be identified. On the medical interview sheets for the 1st and 2nd vaccinations, there was a description that the patient had received permission from the attending physician. See "narrative" section..BP CC: The event developed after the administration of ELASOMERAN and

Case ID	WW Identifier	Narrative Complete
		there is temporal relationship. . ... .Most recent FOLLOW-UP information incorporated above includes:.On 20-Apr-2022: Follow up contains significant information as the dosage text of suspect drug, lab data and patient demographics updated.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 07-Mar-2022 and was forwarded to Moderna on 07-Mar-2022. .This regulatory authority case was reported by a physician and describes the occurrence of DRUG INEFFECTIVE (LACK OF EFFICACY OF DRUG) and VACCINATION FAILURE (VACCINATION FAILURE) in a 66-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214022) for COVID-19 vaccination. . .Co-suspect products included non-company products TOZINAMERAN (COMIRNATY) for COVID-19 vaccination, CASIRIVIMAB, IMDEVIMAB (CASIRIVIMAB;IMDEVIMAB) for COVID-19 prophylaxis, LENALIDOMIDE (REVLIMID) for Non-Hodgkin's lymphoma and OBINUTUZUMAB (GAZYVARO) injection, solution for COVID-19.. .The patient's past medical history included Epigastric hernia, Carpal tunnel syndrome, Tendinopathy, Maxillary sinusitis, Psoriasis, Cyst and Aortic valve insufficiency..Concurrent medical conditions included High cholesterol.. .On 16-Feb-2021, the patient started OBINUTUZUMAB (GAZYVARO) (Intravenous) 1000 milligram..On 10-Mar-2021, the patient received dose of TOZINAMERAN (COMIRNATY) (Intramuscular) 1 dosage form..On 07-Apr-2021, received dose of TOZINAMERAN (COMIRNATY) (unknown route) dosage was changed to 1 dosage form..On 13-Sep-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form..On 27-Sep-2021, the patient started LENALIDOMIDE (REVLIMID) (Oral) 20 milligram..On 25-Oct-2021, the patient started CASIRIVIMAB, IMDEVIMAB (CASIRIVIMAB;IMDEVIMAB) (Intravenous) 600 milligram. On 28-Dec-2021, the patient experienced DRUG INEFFECTIVE (LACK OF EFFICACY OF DRUG) (seriousness criterion death) and VACCINATION FAILURE (VACCINATION FAILURE) (seriousness criterion death). The patient died on 01-Feb-2022. The reported cause of death was Vaccination failure and lack of efficacy of drug. It is unknown if an autopsy was performed. . . .For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered DRUG INEFFECTIVE (LACK OF EFFICACY OF DRUG) and VACCINATION FAILURE (VACCINATION FAILURE) to be related. . .Dosage text of Spikevax was reported as SPIKEVAX...No concomitant medication provided...No treatment medication reported...Company comment:.This regulatory authority case concerns a 66-year-old male patient, who was under treatment with lenalidomide for non-Hodgkin´s lymphoma and had medical history of aortic valve insufficiency, reported serious fatal unexpected event of drug ineffective after a dose of mRNA-1273. Additionally, vaccination failure was also reported. Patient was vaccinated primary COVID-19 vaccine series with two doses of Comirnaty (co-suspect product), hence interchange of vaccine products could also be mentioned in this case. The patient died approximately 4 months after receiving a dose of mRNA-1273 vaccine (COVID-19 vaccine third dose according to vaccination schedule). Reported cause of death were: vaccination failure and lack of drug effect. No information if an autopsy was performed. Co-suspect products and underlying patient disease remain confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
[redacted]		This case was received via European Medicines Agency (Reference number [redacted] on 08-Mar-2022 and was forwarded to Moderna on 08-Mar-2022. .This regulatory authority case was reported by a physician and describes the occurrence of CARDIAC ARREST (Heart arrest) in a 55-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. . .The patient's past medical history included Tobaccoism..Concomitant products included TOZINAMERAN (COMIRNATY) from 05-Jun-2021 to an unknown date for COVID-19 vaccination.. ..On 15-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced CARDIAC ARREST (Heart arrest) (seriousness criterion death). The patient died on 08-Feb-2022. The reported cause of death was post-anoxic coma. An autopsy was not performed. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 22-Jan-2022, Electrocardiogram: no sign of acute ischemia (normal) No sign of acute ischemia..In 2022, SARS-CoV-2 test: negative (Negative) Negative.. . .For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.. .No treatment information was provided...Dosage text for the concomitant medication COMIRNATY was reported as D1+D2...Company comment: This regulatory authority case concerns a 55-year-old male patient with relevant medical history of tobacco use, who experienced serious due to fatal outcome, unexpected event of cardiac arrest, that occurred 8 days the booster dose of the mRNA-1273. Additionally, there was an interchange of vaccine products as the patient was previously vaccinated with two doses of Comirnaty. The reported cause of death was post-anoxic coma. The patient's relevant medical history of smoking is a possible confounder. The benefit-risk relationship of mRNA-1273 is not affected by this report.. .55-year-old man died of cardiac arrest eight days after the booster

Case ID	WW Identifier	Narrative Complete
		dose of the vcovis-19 SPIKEVAX vaccine. The patient has no particular history, apart from active smoking. Absence of argument in favor of a coronary cause or a pulmonary embolism.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 09-Mar-2022 and was forwarded to Moderna on 09-Mar-2022. .This regulatory authority case was reported by a consumer and describes the occurrence of CEREBRAL HAEMORRHAGE (Cerebral hemorrhage) in an 84-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 094F21ABS) for COVID-19 vaccination. . .Previously administered products included for Product used for unknown indication: COMIRNATY on 07-Mar-2021, BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST on 11-Apr-2021..Past adverse reactions to the above products included Dyspnoea with BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST and COMIRNATY.. ..On 14-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 14-Feb-2022, the patient experienced CEREBRAL HAEMORRHAGE (Cerebral hemorrhage) (seriousness criterion death). The patient died on 14-Feb-2022. The reported cause of death was brain hemorrhage, with all consequences. It is unknown if an autopsy was performed. . . . . .No concomitant and treatment information was provided...Company comment: This case concerns an 84-year-old male patient with medical history of interchange of COVID-19 products, who experienced the fatal event of cerebral haemorrhage 2 months after a dose of mRNA-1273. Previous vaccination with BioNTech/Pfizer vaccine, as well as patient's age, could be confounding factors. The reported cause of death was brain hemorrhage. The benefit-risk relationship of mRNA-1273 is not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 09-Mar-2022: Translated document received on 14-Mar-2022 contains English translated verbatim.
[redacted]		This case was initially received via United Kingdom MHRA (Reference number: [redacted] on 10-Mar-2022. The most recent information was received on 18-Mar-2022 and was forwarded to Moderna on 18-Mar-2022. .This regulatory authority case was reported by a consumer and describes the occurrence of LETHARGY (Lethargic), DIZZINESS (Light-headed), NAUSEA (Nausea), DECREASED APPETITE (Appetite lost), VOMITING (Vomiting), ABNORMAL LOSS OF WEIGHT (Unintentional weight loss), PAIN IN EXTREMITY (Pain legs), DEATH (Death unexplained), DYSPNOEA (Dyspnoea), FATIGUE (Fatigue) and ASTHENIA (Asthenia) in a 31-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. . .Co-suspect products included non-company products TOZINAMERAN (COMIRNATY) for COVID-19 vaccination and TOZINAMERAN (COMIRNATY) for COVID-19 vaccination.. .No Medical History information was reported.. .On 28-Jan-2021, the patient received first dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form..On 13-Apr-2021, the patient received second dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form..On 09-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 31-Dec-2021, the patient experienced LETHARGY (Lethargic) (seriousness criterion medically significant) and PAIN IN EXTREMITY (Pain legs) (seriousness criterion medically significant). On 06-Jan-2022, the patient experienced DIZZINESS (Light-headed) (seriousness criterion medically significant), NAUSEA (Nausea) (seriousness criterion medically significant), DECREASED APPETITE (Appetite lost) (seriousness criterion medically significant), VOMITING (Vomiting) (seriousness criterion medically significant) and ABNORMAL LOSS OF WEIGHT (Unintentional weight loss) (seriousness criterion medically significant). On an unknown date, the patient experienced DEATH (Death unexplained) (seriousness criteria death and medically significant), DYSPNOEA (Dyspnoea) (seriousness criterion medically significant), FATIGUE (Fatigue) (seriousness criterion medically significant) and ASTHENIA (Asthenia) (seriousness criterion medically significant). The patient died on 13-Jan-2022. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, LETHARGY (Lethargic), DIZZINESS (Light-headed), NAUSEA (Nausea), DECREASED APPETITE (Appetite lost), VOMITING (Vomiting), ABNORMAL LOSS OF WEIGHT (Unintentional weight loss) and PAIN IN EXTREMITY (Pain legs) had not resolved and DYSPNOEA (Dyspnoea), FATIGUE (Fatigue) and ASTHENIA (Asthenia) outcome was unknown. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On an unknown date, SARS-CoV-2 test: negative (Negative) Negative.. . . . .The dosage text for the suspect product was reported as Dose 3b...Concomitant medications were not provided. Patient was very unsociable and complained of legs aching...On 11-Jan-2022, 17:25, he was not feeling well. He stated that it was not Covid but he had not ate in the past few days, got no appetite, felt really lightheaded and lethargic. Patient said that he got an appointment but it was 2 week wait and was feeling like this since 06-Jan-2022. Patient confirmed that he did all tests right. Patient was feeling lightheaded and not getting any food down. Patient was having food supplements. Treatment medications were not reported...Reaction didn't occurred as a result of a

Case ID	WW Identifier	Narrative Complete
		mistake made in the administration of the vaccine..Company Comment:.This is a regulatory authority case concerning a 31-year-old, male patient with no reported medical history and with vaccine history of receiving 2 doses of another brand of Covid-19 vaccine (Covid-19 vaccine BioNTech) as previous doses, who experienced the unexpected serious (death according to regulatory authority) event of death unexplained and the unexpected serious (medically significant according to regulatory authority) events of lethargy, pain in legs, dizziness, nausea, decreased appetite, vomiting, abnormal loss of weight, dyspnea, fatigue and asthenia. The events lethargic and pain in legs occurred approximately 22 days after the third dose of mRNA-1273 vaccine administration in Covid-19 vaccination in series, the events dizziness, nausea, decreased appetite, vomiting and abnormal loss of weight occurred approximately 28 days after the third dose of mRNA-1273 vaccine administration in Covid-19 vaccination in series, the event death unexplained occurred approximately 35 days after the third dose of mRNA-1273 vaccine administration in Covid-19 vaccination in series while the events dyspnea, fatigue and asthenia occurred after the third dose of mRNA-1273 vaccine administration. On unknown date, patient tested negative on Covid-19 antigen test. It was unknown if autopsy was performed. The reported cause of death was death unexplained. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 18-Mar-2022: Significant follow up received included Lab data, Indication, dose number, dosage text, action taken, dechallenge, rechallenge, event updated.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 10-Mar-2022 and was forwarded to Moderna on 10-Mar-2022. .This regulatory authority case was reported by a physician and describes the occurrence of CARDIOGENIC SHOCK (Cardiogenic shock), ATRIOVENTRICULAR BLOCK (Atrioventricular block) and ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction) in a 93-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. . .Previously administered products included for COVID-19 vaccination: Comirnaty BNT162b2 on 10-Jun-2021 and Comirnaty BNT162b2 on 22-Jul-2021..Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Comirnaty BNT162b2.. ..On 26-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 05-Feb-2022, the patient experienced CARDIOGENIC SHOCK (Cardiogenic shock) (seriousness criteria death, hospitalization and life threatening), ATRIOVENTRICULAR BLOCK (Atrioventricular block) (seriousness criteria death, hospitalization and life threatening) and ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction) (seriousness criteria death, hospitalization and life threatening). The patient died on 05-Feb-2022. The reported cause of death was Cardiogenic shock. It is unknown if an autopsy was performed. . . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .booster vaccination..No concomitant medication were provided..No treatment information were given...Company comment: This regulatory authority case concerns a 93-year-old female patient, with no medical history reported, previously vaccinated with Comirnaty (two doses), who experienced the unexpected fatal AESI of cardiogenic shock, atrioventricular block and myocardial infarction, which all required hospitalization and were additionally considered as life threatening. The events occurred approximately 10 days after the third dose of mRNA-1273. No information regarding clinical course of events or autopsy findings was provided. Reported outcome of all events was fatal. No further information was provided. Patient's advanced age (93) remains as confounder. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness was assessed as per Regulatory Authority reporting.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 11-Mar-2022 and was forwarded to Moderna on 11-Mar-2022. .This regulatory authority case was reported by a physician and describes the occurrence of DYSARTHRIA (slurred speech), DEATH (Death), CIRCULATORY COLLAPSE (Circulatory collapse) and MALAISE (Feeling unwell) in a 48-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 000014A) for COVID-19 vaccination. . .The patient's past medical history included Learning disability (mild) and Coloboma (bilateral)..Concomitant products included COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) from 14-May-2021 to an unknown date for Vaccination, COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) from 21-Mar-2021 to an unknown date for an unknown indication.. ..On 14-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 14-Dec-2021, the patient experienced MALAISE (Feeling unwell) (seriousness criterion death). On 19-Dec-2021, the patient experienced CIRCULATORY COLLAPSE (Circulatory collapse) (seriousness criterion death). On an unknown date, the patient experienced DYSARTHRIA (slurred speech) (seriousness criterion death) and DEATH (Death) (seriousness criterion death). The patient died on 19-Dec-2021. The cause of death was not reported. An autopsy was performed, but no results were provided. . .

Case ID	WW Identifier	Narrative Complete
		.The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown.. .For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.. .Patient had no regular medications. Patient had no history of hypertension, stroke, ischaemic heart disease, thrombocytopenia, or venous thromboemobism. Patient had not symptoms associated with COVID-19. Patient had not a COVID-19 test...Dosage text reported as Dose 3b for Moderna CoviD-19 Vaccine. ..Treatment medications was not reported...Company Comment: This is a fatal case concerning a 48-year-old male patient with previous COVID-19 vaccination using non-company product COVID-19 Vaccine NRVV AD (CHADOX1 NCOV-19), who experienced the unexpected serious events of Malaise, Circulatory Collapse, Dysarthria, and Death. The events led to the eventual demise of the patient as reported by the regulatory authority and occurred 1-6 days after receiving the third dose of mRNA-1273 Vaccine. The patient died 6 days after the vaccine was given and the cause of death was not reported. Autopsy was performed but results were not provided. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 11-Mar-2022 and was forwarded to Moderna on 11-Mar-2022. .This regulatory authority case was reported by a physician and describes the occurrence of PULMONARY EMBOLISM (Pulmonary embolism), DIABETES MELLITUS INADEQUATE CONTROL (Diabetes mellitus inadequate control) and FEELING ABNORMAL (Feeling bad) in a 79-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 017G21A) for Revaccination with different COVID-19 vaccine. The occurrence of additional non-serious events is detailed below. . .The patient's past medical history included Gastroesophageal reflux, Thyroidectomy, Carcinoma breast (treated with surgery and radiotherapy) in 2015 and Cataract operation..Previously administered products included for Product used for unknown indication: COVID-19 Vaccine Janssen on 25-Aug-2021..Past adverse reactions to the above products included No adverse event with COVID-19 Vaccine Janssen..Concurrent medical conditions included Hypothyroidism, Hypertension arterial, Chronic pain (Back chronic pain) and Type 2 diabetes mellitus.. ..On 26-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .5 dosage form. On 26-Jan-2022, the patient experienced COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine), DIABETES MELLITUS INADEQUATE CONTROL (Diabetes mellitus inadequate control) (seriousness criterion medically significant) and FEELING ABNORMAL (Feeling bad) (seriousness criterion medically significant). On 30-Jan-2022, the patient experienced PULMONARY EMBOLISM (Pulmonary embolism) (seriousness criteria death and medically significant). On 26-Jan-2022, COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) had resolved. The patient died on 30-Jan-2022. The reported cause of death was 10084465, 10007617 and 10037377. An autopsy was performed. The autopsy-determined cause of death was Pulmonary embolism. At the time of death, DIABETES MELLITUS INADEQUATE CONTROL (Diabetes mellitus inadequate control) and FEELING ABNORMAL (Feeling bad) had not resolved. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.In October 2021, Laboratory test: normal (normal) blood cell count normal except for moderate lymphopenia, renal function normal, ionogram within normal values, TSH slightly above normal values. HbA1c 9.6%...On 26-Jan-2022, Diabetes mellitus management: abnormal (abnormal) blood sugar imbalance.. . .For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered PULMONARY EMBOLISM (Pulmonary embolism) to be possibly related. No further causality assessments were provided for COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine), DIABETES MELLITUS INADEQUATE CONTROL (Diabetes mellitus inadequate control) and FEELING ABNORMAL (Feeling bad). . .Concomitant medication was not provided...Treatment information was not provided...Company Comment: .This regulatory authority case concerns a 79-year-old, female patient with medical history of Carcinoma breast (treated with surgery and radiotherapy) in 2015 and Concurrent medical condition of Type 2 Diabetes mellitus, who experienced the fatal unexpected serious AESI of Pulmonary embolism and unexpected serious events of Diabetes mellitus inadequate control and Feeling abnormal (seriousness criterion Medically significant). The events Diabetes mellitus inadequate control and Feeling abnormal occurred on the same day and the event Pulmonary embolism occurred 4 days after a dose of mRNA-1273 vaccine administration. The patient died 4 days after the vaccination. The reported causes of death were COVID-19 vaccination, Cardio-respiratory arrest and Pulmonary embolism. The autopsy-determined cause of death was Pulmonary embolism. Additionally, event of COVID-19 immunisation (had a dose of Janssen 5 months 1 day before the current vaccination) interchange of vaccine products is also noted. Patients medical history of Carcinoma breast could be confounding for Pulmonary embolism and Concurrent medical condition of Type 2 Diabetes mellitus could be confounding for Diabetes mellitus inadequate control. The benefit-risk relationship of mRNA-1273 is not affected by this report. The events were assessed as serious as per Regulatory Authority´s report

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[redacted]		This case was received via European Medicines Agency (Reference number: [redacted]) on 11-Mar-2022 and was forwarded to Moderna on 11-Mar-2022. .This regulatory authority case was reported by a consumer and describes the occurrence of CARDIAC ARREST (The day after the injection: feeling as if there was a rubber band around the wrist heart rhythm disorder) and ARRHYTHMIA (The day after the injection: feeling as if there was a rubber band around the wrist heart rhythm disorder) in a 76-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 018J21ABS) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. . .The patient's past medical history included Arrhythmia since an unknown date..Previously administered products included for Product used for unknown indication: BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0,3ML on 29-Mar-2021, BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3ML on 10-May-2021..Past adverse reactions to the above products included No adverse event with BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0,3ML, BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3ML..Concomitant products included DOPAMINE HYDROCHLORIDE (SEMINIET) for an unknown indication.. ..On 29-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 18-Jan-2022, the patient experienced CARDIAC ARREST (The day after the injection: feeling as if there was a rubber band around the wrist heart rhythm disorder) (seriousness criterion death), ARRHYTHMIA (The day after the injection: feeling as if there was a rubber band around the wrist heart rhythm disorder) (seriousness criterion death) and PARAESTHESIA (The day after the injection: feeling as if there was a rubber band around the wrist heart rhythm disorder). The patient died on 18-Jan-2022. The reported cause of death was heart rhythm disorder and followed by cardiac arrest.. It is unknown if an autopsy was performed. At the time of death, PARAESTHESIA (The day after the injection: feeling as if there was a rubber band around the wrist heart rhythm disorder) outcome was unknown. . . . .No treatment information was provided...COMPANY COMMENT : This regulatory authority case concerns a 76-year-old male patient with a relevant past medical history of arrythmia, who experienced the unexpected fatal serious (seriousness criteria death) AESI event of arrhythmia, unexpected serious (seriousness criteria death) event of cardiac arrest, which occurred 20 days after receiving third dose of mRNA- 1273 vaccine. The patient was noted to have received two doses of COMIRNATY 9 months prior to current vaccination with mRNA-1273 (Interchange of vaccine products). It is reported date of death is 18-january-2022, cause of death is arrhythmia and cardiac arrest. Past medical history of arrythmia remains as confounding. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. Events seriousness assessed as per Regulatory Authority reporting.
[redacted]		This case was received via Takeda Pharmaceuticals (Reference number: [redacted] on 11-Mar-2022 and was forwarded to Moderna on 15-Mar-2022. .On 11-Mar-2022, this sponraneous case report was provided by a family member of a vaccine recipient via the Drug Information Center. On 14-Mar-2022, follow-up information was receved from a local official. On an unknown date, the patient received the 1st dose of coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, the patient received the 2nd dose of coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 03-Mar-2022, the patient received the 3rd dose of this vaccine as a municipal group vaccination. On 04-Mar-2022, when a family member spoke to the patient while he was taking a bath, he replied in a sleepy voice. However, the family member went to see the patient after a while and found him drowned. According to a local official, a physician concluded that there was no possibility of suspected adverse reactions. No follow-up investigation will be made. Company Comment: Drowning can be also considered as an accidental disease although it developed after the administration of the ELASOMERAN.
[redacted]		This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted]) on 15-Mar-2022. The most recent information was received on 07-Apr-2022 and was forwarded to Moderna on 15-Apr-2022. .This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, [redacted]). On 07-Apr-2022, follow-up information was received from a physician. On 08-Jun-2021, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, body temperature before the vaccination: 36.7 degrees Celsius. On 24-Feb-2022, at 14:00, the patient received the 3rd vaccination with this vaccine. After the vaccination, the patient did not complain of physical deconditioning. On 25-Feb-2022, at 21:00, the patient was found dead at home. On an unknown date, an autopsy was conducted in the police. A sample of cerebrospinal fluid was taken, and no blood was found; therefore, it was determined that the cause was not in the brain. It is highly likely the sudden death resulting from cardiac causes occurred. The autopsy diagnosis was lethal arrhythmia. The outcome of lethal

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		arrhythmia was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: The causality is unknown because the patient died approximately 24 hours after the vaccination, but it was considered as necessary to make a report of the adverse reactions. If thrombosis occurs in approximately 24 hours (platelet count as high as 587,000), the possibility cannot be ruled out and the onset of adverse events is thus related to the time of administration of the vaccine. The incidence of adverse events is not associated with concomitant drugs because no drug that causes lethal arrhythmia is included in the concomitant drugs. On 25-Jun-2020, the symptoms developed. CAG stated #2 50%, #12 99% delay. PCI was not performed. The occurrence of adverse events is related to the pathological factors of old myocardial infarction, since it is stated that some cardiomyopathy was also considered with high NT proBNP levels. The patient was taking aspirin and understood that hyper thrombocythemia was not a contraindication to vaccination. This was a case in which vaccination was performed as usual, as the patient had been vaccinated twice before. Other contributing factors are unknown. Follow-up received on 07-APR-2022 Updated: Other Relevant History, Product Information, Event Information, Narrative, Reporter Comments Company Comment: Sudden cardiac death occurred after the administration of ELASOMERAN, but it is possible that it was influenced by the concurrent conditions.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 16-Mar-2022 and was forwarded to Moderna on 16-Mar-2022. .This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (cause of death unknown), DEEP VEIN THROMBOSIS (Deep vein thrombosis) and PULMONARY EMBOLISM (Fulminant pulmonary embolism) in an 87-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. . .Previously administered products included for Prophylactic vaccination: Comirnaty on 14-Feb-2021, Comirnaty on 07-Mar-2021 and Comirnaty on 15-Sep-2021..Past adverse reactions to the above products included No adverse event with Comirnaty, Comirnaty and Comirnaty.. ..On 04-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 4 dosage form. In January 2022, the patient experienced DEEP VEIN THROMBOSIS (Deep vein thrombosis) (seriousness criteria hospitalization and life threatening) and PULMONARY EMBOLISM (Fulminant pulmonary embolism) (seriousness criteria hospitalization and life threatening). The patient died on 23-Jan-2022. The cause of death was not reported. An autopsy was performed, but no results were provided. At the time of death, DEEP VEIN THROMBOSIS (Deep vein thrombosis) and PULMONARY EMBOLISM (Fulminant pulmonary embolism) had not resolved. . . . .Post-mortal: SARS-CoV-2 infection without symptoms..No Concomitant medication information was reported..No treatment medications were provided...Company comment: This Fatal Regulatory Authority case concerns a 87-year-old, female patient, with no reported medical history, who experienced the unexpected, serious (life threatening/ hospitaliation) AESI of deep vein thrombosis and pulmonary embolism in the same month after receiving a dose of mRNA-1273 vaccine, exact events dates were not reported. She received 3 doses of Cominarty's COVID-19 vaccine previously. The patient died 19 days after vaccination, cause of death was reported as unknown. Autopsy report is not available. No further clinical information was provided for medical reviewing. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.
[redacted]		This case was initially received via Takeda Pharmaceuticals (Reference number [redacted] on 15-Mar-2022. The most recent information was received on 05-Apr-2022 and was forwarded to Moderna on 13-Apr-2022. .This case was reported by a physician via a medical representative. On 05-Apr-2022, follow-up information was received from a physician. The vaccine recipient was being treated for hypertension, dyslipidaemia, osteoporosis, and Alzheimer's type dementia. On 16-Jun-2021, the patient received the 1st dose of coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 07-Jul-2021, the patient received the 2nd dose of coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 07-Mar-2022, in the morning, the patient received the 3rd vaccination with this vaccine. On 08-Mar-2022, in the early evening, the patient experienced inability to eat due to sleepiness. Thereafter, faecal incontinence developed. The patient was transported to a hospital by ambulance. During transport, the patient suffered from cardio-respiratory arrest. The patient died. A postmortem CT in the hospital where the patient was transported diagnosed the symptoms as pneumonia and sepsis. No autopsy was performed. The outcome of cardio-respiratory arrest, pneumonia, and sepsis was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: The occurrence of adverse events is not related to pathological factors of underlying diseases and complications because they had developed for quite some time and no problem was guessed. Adverse reactions are not related to the case of death. The patient was diagnosed with pneumonia and sepsis in the hospital where the patient was transported, and the relationship is not considered. However, proximity of time is considered as a problem. Follow-up received on 05-APR-2022 Updated: Other Relevant History, Lab Data, Product Information, Event

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		Information, Narrative, Reporter Comments Company Comment: Pneumonia and sepsis can be also considered as an accidental disease although it developed after the administration of ELASOMERAN.
[redacted]		This regulatory authority case was reported by an other health care professional and describes the occurrence of FATIGUE (Fatigue), SOMNOLENCE (Drowsiness) and ASTHMA (Asthma) in an 89-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. . .The patient's past medical history included Osteoporosis..Previously administered products included for Product used for unknown indication: (AZ) covid-19 vaccines (Received Dose 1 and 2 (AZ) covid-19 vaccines) on 16-Jun-2021 and (AZ) covid-19 vaccines (Received Dose 1 and 2 (AZ) covid-19 vaccines) on 16-Sep-2021..Past adverse reactions to the above products included No adverse effect with (AZ) covid-19 vaccines and (AZ) covid-19 vaccines.. ..On 22-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 07-Feb-2022, the patient experienced FATIGUE (Fatigue) (seriousness criterion death), SOMNOLENCE (Drowsiness) (seriousness criterion death) and ASTHMA (Asthma) (seriousness criterion death). The patient died on 07-Feb-2022. The reported cause of death was Fatigue, Drowsiness and Asthma. It is unknown if an autopsy was performed. . . .For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.. .Relevant concomitant medications were not reported..On 11-Mar-2022: The family reported a case of suspected COVID-19 vaccine related adverse reaction (death). Patient started to have wheezing during climbing stairs on 01-Feb and then fatigue, somnolence, and inappetence. In the morning of 07-Feb, her son had planned to take the patient to the hospital outpatient, but the patient said no. The patient was found to fall unconsciously in the bathroom by her family at 10 PM on the same day. She was sent to hospital ER after emergency CPR, but the first aid failed. The patient died on 07-Feb-2022...Company comment: This is a regulatory authority case concerning a 89-year-old, female patient initially vaccinated with two doses of Covid 19 vaccine Astra Zeneca with no reported adverse events . who experienced the Serious (death) unexpected , events of Fatigue, Somnolence, Wheezing. The events occurred 16 days after vaccination with the third dose of mRNA-1273 COVID 19 Vaccine. This patient started to have wheezing during climbing stairs on Feb 1 and then fatigue, somnolence, and inappetence (9 days post vaccination with the third dose of the mRNA-1273 vaccine) . In the morning of Feb 7 (16 days post vaccination , her son had planned to take the patient to the Lukang Christian Hospital outpatient, but the patient refused. . The same day at 10 pm this patient was found to fall unconsciously in the bathroom by her family . She was sent to Lukang Christian Hospital ER where CPR was done but the first aid failed. The patient died on Feb 7, 2022. No further information was reported surrounding the death of this patient like treatment medication and official report from the hospital as the cause of death and it is unknown if an autopsy was done. The age of this patient and the history of initial vaccination with two doses of Covid 19 vaccine Astra Zeneca is considered as confounder for the fatal outcome of the events . The benefit -risk relationship of mRNA -1273 (Moderna Covid 19 Vaccine) is not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 25-Apr-2022: Patient demographic, history, death date, cause of death, product indication, event details updated.
[redacted]		This regulatory authority case was reported by an other health care professional and describes the occurrence of FATIGUE (Fatigue), PAIN IN EXTREMITY (Limb pain), PYREXIA (Fever) and VACCINATION SITE PAIN (vaccination site pain) in a 55-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. . .Previously administered products included for COVID-19 vaccination: AZ Vaccine (Dose 1) on 23-Jul-2021 and AZ Vaccine (Dose 2) on 20-Oct-2021..Past adverse reactions to the above products included No adverse event with AZ Vaccine and AZ Vaccine..Concurrent medical conditions included Diabetes.. ..On 22-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 23-Jan-2022, the patient experienced FATIGUE (Fatigue) (seriousness criterion death), PAIN IN EXTREMITY (Limb pain) (seriousness criterion death), PYREXIA (Fever) (seriousness criterion death) and VACCINATION SITE PAIN (vaccination site pain) (seriousness criterion death). The reported cause of death was Fatigue, limb pain, Fever and Vaccination site pain. An autopsy was performed. The autopsy-determined cause of death was suspected arrhythmia and right ventricular cardiomyopathy and suspected arrhythmia and right ventricular cardiomyopathy. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 27-Jan-2022, SARS-CoV-2 test: negative (Negative) Negative..On an unknown date, Antibody test: not reported Not reported.. . .For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.. .No concomitant medications were reported..On 23 Jan 2022, the patient had fever, arm pain, extreme fatigue, somnolence. On 25 Jan 2022, he showed up for work afternoon and disappeared hours later. On 26 Jan 2022, policeman found patient lying supine in back seat and trunk of vehicle with no vital signs. The vehicle was not started but windows were lowered. After the body was turned over, a lot of fluid spilled. No visible fatal injury. He was confirmed dead.

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		On 27 Jan 2022, an autopsy was performed.No treatment medications were reported..The Worldwide UID was reported as [redacted]..Company comment: This regulatory authority case concerns a 55-year-old, male patient, with relevant medical history of Diabetes Mellitus , initially received two doses of Covid 19 vaccine Astra Zeneca with no reported adverse events. who experienced the Serious (fatal) unexpected events of Fatigue, Pain in extremity, Pyrexia and Vaccination site pain which occurred 1 day post vaccination with the third dose of mRNA-1273..This patient was reported to have fever, arm pain, extreme fatigue, somnolence one day post vaccination with the third dose of mRNA -1273 vaccine . Three days post vaccination this patient went to work however that afternoon he became uncontactable. The family members called police and they started to search for patient. On Jan, 26, 2022, 4 days post vaccination with the third dose of mRNA-1273 vaccine a policeman found the patient lying supine in back seat and trunk of vehicle and there were no signs of life. The vehicle was not started but some windows were lowered. There was a large amount of spilled out of the corpse after the body was turned. There was no visible sign of fatal injury. This case was confirmed as a death . An autopsy was performed the day after the death and the preliminary judicial autopsy report:: suspected arrhythmia and right ventricular cardiomyopathy. Outcome of the events was reported as fatal per regulatory report. The history of Diabetes Mellitus and the history of previous vaccination with Covid 19 vaccine Astra Zeneca of this patient may be considered as a confounders for the outcome of death and the possible heart condition mentioned in the autopsy report. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Events' seriousness assessed as per regulatory report.. .Most recent FOLLOW-UP information incorporated above includes:.On 25-Apr-2022: Follow-up received on 25 Apr 2022 as the event changed from injection site pain to vaccination site pain, historical vaccine and lab data was added.
[redacted]		This case was initially received via European Medicines Agency (Reference number: [redacted] on 16-Mar-2022. The most recent information was received on 18-Mar-2022 and was forwarded to Moderna on 18-Mar-2022. .This regulatory authority case was reported by a physician and describes the occurrence of PULMONARY EMBOLISM (Pulmonary embolism) and CARDIAC ARREST (Cardiac arrest) in a 78-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004498) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. . .Co-suspect products included non-company products TOZINAMERAN (COMIRNATY) for Vaccination and TOZINAMERAN (COMIRNATY) for Vaccination.. .No Medical History information was reported.. .On 31-Mar-2021, the patient received first dose of TOZINAMERAN (COMIRNATY) (Intramuscular) 1 dosage form..On 12-May-2021, the patient received second dose of TOZINAMERAN (COMIRNATY) (Intramuscular) 1 dosage form..On 18-Nov-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 09-Feb-2022, the patient experienced PULMONARY EMBOLISM (Pulmonary embolism) (seriousness criterion death) and CARDIAC ARREST (Cardiac arrest) (seriousness criterion death). On an unknown date, the patient experienced COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine). The patient died on 20-Feb-2022. It is unknown if an autopsy was performed. At the time of death, COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) outcome was unknown. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 09-Feb-2022, Computerised tomogram: ct detected large pulmonary embolies (abnormal) CT detected large pulmonary embolies.. . .For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered PULMONARY EMBOLISM (Pulmonary embolism) and CARDIAC ARREST (Cardiac arrest) to be possibly related. No further causality assessment was provided for COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine). . .No concomitant medication was reported..No treatment medication was reported...Report number-[redacted] was found to be a duplicate for Report number-[redacted] upon receipt of follow up. All information kept in [redacted] (this report) and report [redacted] had been nullified...Company comment: This regulatory case concerns a 78-year-old, male patient with no reported medical history, who experienced the unexpected, fatal AESI Pulmonary embolism and unexpected, fatal event of Cardiac arrest. COVID-19 immunisation was reported as an additional event wherein 2 doses of Tozinameran COVID-19 vaccine were administered 6 months prior to mRNA-1273. The events occurred approximately 3 months after receiving mRNA-1273 as booster dose, where CT scan was done which revealed large pulmonary emboli. The patient was then admitted to the medical intensive care where unspecified treatment was administered. Presenting symptoms and initial vital signs were not specified in the case. No direct cause for the pulmonary embolism was found. Prior cardiac arrest has resulted to significant brain damage. The patient died 11 days after events onset. It is unknown if autopsy was performed. The elderly age of the patient remains a confounder for the events and for the fatal outcome. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per

Case ID	WW Identifier	Narrative Complete
		Regulatory Authority's report.. .Most recent FOLLOW-UP information incorporated above includes:.On 18-Mar-2022: Follow up received contains updated date of death, lab data and reporter's comment.
[redacted]	[redacted]	This case was received via Takeda Pharmaceuticals (Reference number: [redacted]) on 16-Mar-2022 and was forwarded to Moderna on 18-Mar-2022. . This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, [redacted]). Fracture of the left caput humeri and suspected hemodyscrasia was assessed as serious by the MAH. On an unknown date, the patient received the 1st dose of coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, the patient received the 2nd dose of coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, body temperature before vaccination: 35.2 degrees Celsius. On 28-Feb-2022, at 13:15, the patient received the 3rd vaccination with this vaccine. On an unknown date, fracture of the left caput humeri developed. Around 04-Mar-2022, swelling, pain, and internal hemorrhage of the left upper arm were noted. On 07-Mar-2022, the patient went to see a nearby physician. No specific tests were performed, but hemodyscrasia was suspected. After returning home, the patient lost consciousness and was transported to the reporting hospital in a cardio-respiratory arrest state. There was no response to treatment. Test results after cardiac arrest included AST 754, LDH 1,665, CK 1,112 (CKMB 25), and K 12.6. At 16:55, the patient's death was confirmed. The outcome of fracture of the left caput humeri and suspected hemodyscrasia was unknown. The outcome of swelling of the left upper arm, pain, internal hemorrhage, consciousness loss, and cardio-respiratory arrest was reported as fatal. Follow-up investigation will be made. Reporter comments continuation: Since the memory of the family members is vague, the relationship between before and after is unclear, but since there is also a fracture of the left caput humeri, it is likely that this was the main cause of the swelling in the left upper arm, and the degree of involvement of this vaccine is unknown. Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
[redacted]	[redacted]	This case was received via European Medicines Agency (Reference number: [redacted]) on 18-Mar-2022 and was forwarded to Moderna on 18-Mar-2022. .This regulatory authority case was reported by a physician and describes the occurrence of HYPERSENSITIVITY (Allergic reaction) and DEATH (cause of death unknown) in a female patient of an unknown age who received mRNA-1273 (Spikevax) for COVID-19 vaccination. . .Previously administered products included for Prophylactic vaccination: Comirnaty BNT162b2 on 23-Apr-2021 and Comirnaty BNT162b2 on 04-Jun-2021..Past adverse reactions to the above products included No adverse reaction with Comirnaty BNT162b2 and Comirnaty BNT162b2.. ..On 13-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 3 dosage form. On 17-Jan-2022, the patient experienced HYPERSENSITIVITY (Allergic reaction) (seriousness criterion medically significant). The patient died on 27-Feb-2022. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, HYPERSENSITIVITY (Allergic reaction) outcome was unknown. . . .The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown.. .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .No concomitant medication details were reported..No treatment medication details were reported...Company Comment : This regulatory authority case concerns a female patient of unknown age initially vaccinated with two doses of Covid 19 vaccine Pfizer with no reported adverse events, who experienced Serious (medically significant) , unexpected event of Hypersensitivity which occurred 4 days post vaccination with an unknown dose number of mRNA-1273 vaccine (reported as 3 dosage forms) . This was accompanied by another Serious (fatal) , unexpected event of death which occurred 1 month 14 days post vaccination with the unknown dose number of mRNA-1273 (3 dosage form) . The details surrounding the events and treatment details were not reported . The cause of death of this patient was reported as unknown and it was also unknown if an autopsy was done. The history of vaccination with Covid 19 vaccine Pfizer for two doses , event of hypersensitivity reaction and the reported 3 dosage forms administered to the patient are considered as confounders for the event of death . Event of interchange of vaccine products and possible accidental overdose occurred . The benefit -risk relationship of mRNA -1273 (Moderna Covid 19 Vaccine) is not affected by this report..
[redacted]	[redacted]	This case was received via European Medicines Agency (Reference number: [redacted]) on 18-Mar-2022 and was forwarded to Moderna on 18-Mar-2022. .This regulatory authority case was reported by a consumer and describes the occurrence of ABDOMINAL PAIN (After vaccination nausea, abdominal pain, blood vomiting, emergency doctor, deceased...), NAUSEA (After vaccination nausea, abdominal pain, blood vomiting, emergency doctor, deceased...) and HAEMATEMESIS (Death, Blood Surrendered) in an elderly male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. ..The patient's past medical history included Ex-smoker (Quit smoking more than 40 years ago)..Previously administered products included for Product used for unknown indication: COVID-19 VACCINE on 24-Mar-2021 and PFIZER BIONTECH COVID-19

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		VACCINE on 06-May-2021..Past adverse reactions to the above products included No adverse reaction with COVID-19 VACCINE and PFIZER BIONTECH COVID-19 VACCINE.. ..On 03-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, the patient experienced ABDOMINAL PAIN (After vaccination nausea, abdominal pain, blood vomiting, emergency doctor, deceased...) (seriousness criterion death), NAUSEA (After vaccination nausea, abdominal pain, blood vomiting, emergency doctor, deceased...) (seriousness criterion death) and HAEMATEMESIS (Death, Blood Surrendered) (seriousness criterion death). The patient died on 06-Dec-2021. The reported cause of death was blood vomiting. An autopsy was not performed.. . . . .No concomitant medication was reported..No treatment information was reported...Company comment-This regulatory case concerns an elderly male patient of unknown age, ex-smoker with no other relevant medical history reported, who experienced the unexpected serious fatal events of Abdominal pain, Nausea and Haematemesis which occurred at an unknown interval after a dose of mRNA-1273 vaccine. Patient died 3 days after vaccination. The cause of death was reported as Vomiting blood and Unknown cause of death. It was reported that after vaccination nausea, abdominal pain, blood vomiting consulted emergency doctor. No clinical or treatment details were given. Later reported as deceased.An autopsy was not performed. The patient had received initial schedule of vaccination with COMIRNATY (interchange of vaccine products was noted). Patient's elderly age and he being an ex-smoker remains as confounders to the event Haematemesis. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. The events were assessed as serious as per Regulatory Authority's report.. .Most recent FOLLOW-UP information incorporated above includes:.On 18-Mar-2022: Translated document received on 24-MAR-2022, it contains non significant information (event verbatim and medical history translated).
[redacted]	[redacted]	This case was initially received via United Kingdom MHRA (Reference number: [redacted] on 22-Mar-2022. The most recent information was received on 12-Apr-2022 and was forwarded to Moderna on 12-Apr-2022. .This regulatory authority case was reported by a consumer and describes the occurrence of CONTUSION (Bruising), YELLOW SKIN (Yellow skin), CARDIOPULMONARY FAILURE (Cardio-respiratory failure), RESPIRATORY TRACT INFECTION (Respiratory tract infection), FACIAL PARALYSIS (Facial droop), FALL (Falling), the first episode of ASTHENIA (Weakness), the second episode of ASTHENIA (Weakness), PAIN IN EXTREMITY (Pain in arm) and EPISTAXIS (Nose bleed) in a 57-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. . .Co-suspect product included non-company product INFLUENZA VACCINE (INFLUENZA VIRUS) for Influenza immunisation.. .The patient's past medical history included Chronic obstructive pulmonary disease, Chest infection, Bipolar disorder and Dissociative disorder..Previously administered products included for COVID-19 vaccination: COVID-19 VACCINE ASTRAZENECA on 15-Mar-2021 and COVID-19 VACCINE ASTRAZENECA on 17-Jun-2021..Past adverse reactions to the above products included No adverse event with COVID-19 VACCINE ASTRAZENECA and COVID-19 VACCINE ASTRAZENECA..Concomitant products included FLUTICASONE FUROATE, VILANTEROL TRIFENATATE (RELVAR ELLIPTA [FLUTICASONE FUROATE;VILANTEROL TRIFENATATE]), UMECLIDINIUM BROMIDE (INCRUSE ELLIPTA), ZOPICLONE (ZIMOVANE), QUETIAPINE FUMARATE (SONDATE XL), ATORVASTATIN, CARBOCISTEINE, PREGABALIN, DIAZEPAM, MIRTAZAPINE, VITAMIN D NOS and GLYCERYL TRINITRATE for an unknown indication.. .On 17-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form and dose of INFLUENZA VACCINE (INFLUENZA VIRUS) (unknown route) 1 dosage form. On 17-Dec-2021, the patient experienced CONTUSION (Bruising) (seriousness criterion medically significant) and YELLOW SKIN (Yellow skin) (seriousness criterion medically significant). On 24-Dec-2021, the patient experienced CARDIOPULMONARY FAILURE (Cardio-respiratory failure) (seriousness criteria death and medically significant) and RESPIRATORY TRACT INFECTION (Respiratory tract infection) (seriousness criteria death and medically significant). On an unknown date, the patient experienced FACIAL PARALYSIS (Facial droop) (seriousness criterion medically significant), FALL (Falling) (seriousness criterion medically significant), the first episode of ASTHENIA (Weakness) (seriousness criterion medically significant), the second episode of ASTHENIA (Weakness) (seriousness criterion medically significant), PAIN IN EXTREMITY (Pain in arm) (seriousness criterion medically significant) and EPISTAXIS (Nose bleed) (seriousness criterion medically significant). The patient died on 24-Dec-2021. The reported cause of death was Respiratory tract infection and Cardio-respiratory failure. An autopsy was performed, but no results were provided. At the time of death, CONTUSION (Bruising) and YELLOW SKIN (Yellow skin) had not resolved and FACIAL PARALYSIS (Facial droop), FALL (Falling), the last episode of ASTHENIA (Weakness), PAIN IN EXTREMITY (Pain in arm) and EPISTAXIS (Nose bleed) outcome was unknown. . . . .The concomitant medications were reported as Atorvastatin 20mg OD,

Case ID	WW Identifier	Narrative Complete
		Zimovane 7.5mg x3 at night ,Incruse ellipta 55mcgs inhaler OD , relvar ellipta 92mcgs OD , mirtazapine 45mg OD , diazepam 5mg x3 morn 1x lunchtime 1 x teatime, .Pregabalin 300mg x1 twice daily , sondate XL 200mg, Once at night Carbocisteine 750mg OD and also high dose of vitamin D AND ANGINA spray for evening..It was reported that the patient was given both moderna and flue vaccine on the same day . Patient was a vulnerable adult and had certain medical conditions that made her immune system weak. Reporter said that the events happened due to mistake made in the administration of the vaccine. Patient complained to the doctor regarding yellow spots and brushing of her veins in the arm in which the.Moderna was given and the site used may have been incorrect and depth of injection, the handling of theactual vaccine before administration as this was done.by a general practitioner practice...The treatment information was not reported.. .Most recent FOLLOW-UP information incorporated above includes:.On 12-Apr-2022: Significant Follow-up was received. Added reason of death and events ,concomitant medication ...Company Comment.This is a fatal regulatory case concerning a 57-year-old female patient with medical history of chronic obstructive pulmonary disease and chest infection, who experienced the serious unexpected events of respiratory tract infection, cardiopulmonary failure, fall, contusion, yellow skin, asthenia, pain in extremity, epistaxis, and the expected event of facial paralysis. The events occurred approximately one week after a dose of mRNA-1273, considered as third dose of her COVID – 19 immunization schedules; the patient previously had two doses of AstraZeneca COVID-19 vaccine approximately 6 months prior (interchange of vaccine products could be considered). On the same day of vaccination with mRNA - 1273 the patient also received the influenza virus vaccine. It is reported that patient was a vulnerable adult with a condition of a weak immune system, who had previously been under nurse care due to a chest infection. The reporter mentioned the patient had yellow spots and brushing of her veins in the arm in which mRNA – 1273 was given, with pain of this extremity. On an unspecified date, she was feeling unwell, weak, and lethargic, had facial drooping and nosebleed. The patient was taken in a private ambulance and was presumably treated with glyceryl trinitrate spray. Death occurred seven days after vaccination with mRNA - 1273, and the cause of death was reported as respiratory tract infection with aspiration and cardio – respiratory failure. Autopsy was performed although the result was not available for medical review. Co – suspect product Influenza Virus Vaccine remains as confounder. Patient concurrent condition chronic obstructive pulmonary disease and medical history of chest infection remains a confounder for respiratory tract infection and cardiopulmonary failure. The benefit-risk relationship of mRNA-1273 is not affected by this report.
[redacted]		This case was received via Takeda Pharmaceuticals (Reference number: [redacted] on 18-Mar-2022 and was forwarded to Moderna on 23-Mar-2022. .This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, [redacted]). Cerebral infarction and decreased level of consciousness was assessed as serious by the MAH. On 25-Jun-2021, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 16-Jul-2021, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, body temperature before the vaccination: 37.0 degrees Celsius. On 15-Mar-2022, at 14:00, the patient received the 3rd vaccination with this vaccine. Around 16:00, pyrexia of 38.0-38.9 degrees Celsius developed. On an unknown date, pyrexia of 39 degrees Celsius to 40 degrees Celsius persisted. The patient was recommended to take acetaminophen but refused. On 17-Mar-2022, drip infusion was started because insufficient fluid intake was noted. The patient was able to answer calls and talk. On 18-Mar-2022, in the morning, decreased level of consciousness and decreased blood pressure were noted. Computed tomography (CT) of the head, chest, and abdomen was performed to determine the cause. There was no cause of decreased level of consciousness from the chest to the abdomen. However, head CT showed cerebral infarction in the left frontal region, which appeared to be in the acute phase. Intratracheal intubation and drip infusion were performed. At 11:10, the patient died. The outcome of pyrexia, decreased level of consciousness, decreased blood pressure, and cerebral infarction was unknown. Follow-up investigation will be made... Company Comment: Cerebral infarction occurred after the administration of ELASOMERAN, but it is possible that it was influenced by complications, the patient's background and others. Also, death occurred after the administration of ELASOMERAN, but it is possible that it was influenced by concomitant events and others.
[redacted]		This case was initially received via European Medicines Agency (Reference number: [redacted] on 21-Mar-2022. The most recent information was received on 23-Mar-2022 and was forwarded to Moderna on 23-Mar-2022. .This regulatory authority case was reported by a physician and describes the occurrence of CARDIAC FAILURE ACUTE (according to postmortem on heart failure) in a 67-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004670) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. . .The patient's past medical history included Pulmonary embolism (Pulmonary

Case ID	WW Identifier	Narrative Complete
		embolism) in 2014..Previously administered products included for COVID-19 immunisation: COMIRNATY (Booster after 2x Comirnaty) and COMIRNATY (Booster after 2x Comirnaty)..Past adverse reactions to the above products included No adverse event with COMIRNATY and COMIRNATY..Concurrent medical conditions included Hypertension (hypertension), Cardiac hypertrophy (Global cardiac hypertrophy and dilatation), Hepatic steatosis (Fatty liver disease), Anxiety disorder (anxiety disorder that was well controlled), Cardiac dilatation (Global cardiac hypertrophy and dilatation) and Blood pressure high (was well controlled).. ..On 27-Nov-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 27-Nov-2021, after starting mRNA-1273 (Spikevax), the patient experienced COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine). In December 2021, the patient experienced CARDIAC FAILURE ACUTE (according to postmortem on heart failure) (seriousness criterion death). The patient died on 09-Dec-2021. The reported cause of death was acute heart failure primarily rhythmogenic. An autopsy was performed. The autopsy-determined cause of death was acute heart failure primarily rhythmogenic. At the time of death, COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) outcome was unknown. . . .For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.. .No concomitant medications were reported...The time of death was reported as 04:42 and dosage text was reported as third partial vaccination / third dose heterologous...No treatment details were reported...Company comment:.This regulatory authority fatal case concerns a 67-year-old male patient, with medical history of Cardiac hypertrophy, Cardiac dilatation, Hypertension, Pulmonary embolism and Hepatic steatosis, who experienced the unexpected serious fatal AESI of CARDIAC FAILURE ACUTE, which occurred approximately 12 days after receiving a dose of mRNA-1273 vaccine, considered as the third dose for COVID19 vaccination (received Comirnaty as doses 1 and 2). The patient died on 09-Dec-2021. The reported cause of death was acute heart failure primarily rhythmogenic. The autopsy-determined cause of death was acute heart failure primarily rhythmogenic. The mentioned medical history remains as a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event's seriousness assessed as reported.. .Most recent FOLLOW-UP information incorporated above includes:.On 23-Mar-2022: Follow-up received was updated with relevant medical history, cause of death and event cardiac failure was updated to acute cardiac insufficiency..On 23-Mar-2022: Translation received on 31-Mar-2022 that contains non significant information includes event verbatim updated.
[redacted]	[redacted]	This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 24-Mar-2022. The most recent information was received on 13-Apr-2022 and was forwarded to Moderna on 20-Apr-2022. .This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref. [redacted]). On 13-Apr-2022, follow-up information was received from a physician. On an unknown date, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, body temperature before the vaccination: 36.5 degrees Celsius. On 09-Mar-2022, at 19:00, the patient received the 3rd vaccination with this vaccine. On 10-Mar-2022, although headache and malaise were noted, the patient had a daily life as usual. Around 22:00, the patient took a bath. At 22:40, the patient was found in a state of cardio-respiratory arrest in the bathtub. On 11-Mar-2022, resuscitation was attempted, but the patient had no response and died. A CT scan indicated that water was taken into the patients lung. The cause of death was near drowning. The direct cause of death was near drowning, but the cause of near drowning is unknown. Myocardial infarction or fatal arrhythmia may have occurred. The outcome of headache and malaise was unknown. The outcome of cardio-respiratory arrest, near drowning, possibility of myocardial infarction, and possibility of lethal arrythmia was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: The patient had underlying diseases of diabetes mellitus and dyslipidemia, and a disease such as myocardial infarction cannot be ruled out; therefore, it is unknown whether the occurrence of adverse events is related to pathological factors of underlying diseases and complications. Thrombotic tendency developed after vaccination with this vaccine, and thus occurrence of myocardial infarction or others cannot be ruled out. The cause of death and adverse events are related because the cause of near drowning is unknown, and the causal relationship cannot be ruled out. Follow-up received on 13-APR-2022 Updated: Patient Information, Other Relevant History, Lab Data, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 28-Mar-2022 and was forwarded to Moderna on 28-Mar-2022. .This regulatory authority case was reported by a physician and describes the occurrence of CAROTID ARTERY

Case ID	WW Identifier	Narrative Complete
		THROMBOSIS (Thrombosis carotid) and ISCHAEMIC STROKE (Ischemic stroke) in a 62-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 214029) for COVID-19 vaccination. . .The patient's past medical history included Breast injury..Previously administered products included for COVID-19 vaccination: COMIRNATY (Vaccin Pfizer Comirnaty 30) on 29-Jun-2021 and COMIRNATY (Vaccin Pfizer Comirnaty 30) on 20-Jul-2021..Past adverse reactions to the above products included No adverse reaction with COMIRNATY and COMIRNATY..Concurrent medical conditions included Morbid obesity, Non-insulin-dependent diabetes mellitus and Arterial hypertension..Concomitant products included HYDROCHLOROTHIAZIDE, AMLODIPINE BESILATE (AMLOR) and CANDESARTAN CILEXETIL for Arterial hypertension, METFORMIN (METFORMINE [METFORMIN]) for Non-insulin-dependent diabetes mellitus, RABEPRAZOLE SODIUM (PARIET) for an unknown indication.. ..On 14-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 20-Feb-2022, the patient experienced CAROTID ARTERY THROMBOSIS (Thrombosis carotid) (seriousness criteria death, hospitalization and life threatening) and ISCHAEMIC STROKE (Ischemic stroke) (seriousness criteria death, hospitalization and life threatening). The patient died on 22-Feb-2022. The reported cause of death was brain death following a complication of ischemic stroke. It is unknown if an autopsy was performed. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 20-Feb-2022, Magnetic resonance imaging head: occlusion of the right internal carotid (abnormal) occlusion of the right internal carotid and of the middle cerebral artery, thrombus in T2 hyposignal, long which seems to extend from the carotid siphon to the M1 segment, complete right sylvian ischemic stroke visible in diffusion but not yet in flair...On an unknown date, SARS-CoV-2 test: negative (Negative) Negative.. . .For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.. .A 62-year-old patient, morbidly obese, diabetic and hypertensive, who died following a right sylvian ischemic stroke approximately 5 and a half weeks after being vaccinated with SPIKEVAX (booster dose, after complete initial vaccination schedule at 2 doses with COMIRNATY 6 months earlier)...Dosage text was reported as R1...Treatment information was not provided...Company comment:.This regulatory authority case concerns a 62-year-old female patient, with relevant medical history of Arterial Hypertension, morbid obesity and diabetes mellitus non-insulin-dependent, previously vaccinated with two doses of Cominarty, who experienced the serious (fatal, life-threatening and hospitalization) unexpected AESI of Ischaemic Stroke and Carotid Artery Thrombosis, 37 days after a dose of mRNA-1273 (reported as R1). The events could be in association with each other. The patient died 39 days after vaccination, and cause of death was reported as brain death following a complication of ischemic stroke. It is unknown if an autopsy was performed. Patient's mentioned medical history remains contributing factors. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 28-Mar-2022: Translation document received on 29-Mar-2022 included Lab data test name updated.
[redacted]		This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 29-Mar-2022. The most recent information was received on 14-Apr-2022 and was forwarded to Moderna on 21-Apr-2022. . This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a (physician), was received via the PMDA (Ref, [redacted]. On 14-Apr-2022, follow-up information was received from a physician. On 04-Jun-2021, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 25-Jun-2021, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, body temperature before the vaccination: 36.4 degrees Celsius. On 09-Feb-2022, at 14:30, the patient received the 3rd vaccination with this vaccine. On 10-Feb-2022, in the afternoon, depressed level of consciousness was noted, and the patient visited a medical institution. Blood collection was performed, and drip infusion was attempted but did not go in. The patient was advised to be hospitalized but refused and returned home. Depressed level of consciousness was resolving. On 11-Feb-2022, around 11:00, the family member found the patient dead. No autopsy was performed, and postmortem examination was performed. The cause of death was unknown. The outcome of depressed level of consciousness was reported as resolving. No follow-up investigation will be made. Reporter comments continuation: The relationship between the occurrence of adverse events and pathological factors such as underlying diseases and complications is unknown. The relationship between the cause of death and adverse events is unknown. The causality is unknown. The drugs the patient took are unspecified except aspirin. Follow-up received on 14-APR-2022 Updated: Patient Information, Other Relevant History, Product Information, Event Information, Narrative, Reporter Comments Company Comment: Depressed level of consciousness and death could also be due to a past medical history or an accidental disease although it developed after the administration of ELASOMERAN.

Case ID	WW Identifier	Narrative Complete
[redacted]	[redacted]	This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted]) on 30-Mar-2022. The most recent information was received on 14-Apr-2022 and was forwarded to Moderna on 21-Apr-2022. .This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref,[redacted]. On 14-Apr-2022, follow-up information was received by a physician. On 18-Apr-2022, follow-up information was reported by a healthcare professional via the Drug Information Center. The vaccine recipient had regular visits to a hospital. On 24-Jul-2021, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 13-Aug-2021, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, body temperature before the vaccination: 36.6 degrees Celsius. On 28-Mar-2022, at 11:30, the patient received the 3rd vaccination with this vaccine. At 20:00, after dinner, the patient went to bed. On 29-Mar-2022, around 01:00, the patient went to the bathroom with assistance. Around 03:00, the family member woke the patient up to encourage her to go to the bathroom. However, the patient was in a state of unconsciousness. An emergency call was made immediately, and the patient was raced to an emergency hospital. At 05:34, death was confirmed. The cause of death was unknown. No autopsy was performed. The outcome of the patient had no consciousness was unknown. No follow-up investigation will be made. Reporter comments continuation: Since adverse events developed within 24 hours after the vaccination, there was a relationship between the cause of death and adverse events. Adverse events developed within 24 hours after vaccination, and other factors cannot be ruled out, but details are unknown. Follow-up received on 14-APR-2022 Updated: Reporter Information, Patient Information, Other Relevant History, Product Information, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
[redacted]	[redacted]	This case was received via European Medicines Agency (Reference number: [redacted]) on 30-Mar-2022 and was forwarded to Moderna on 30-Mar-2022. . .This regulatory authority case was reported by a consumer and describes the occurrence of GRANULOMATOSIS WITH POLYANGIITIS (After the 3rd vaccination on 18.12.2021, a strong outbreak of granulatosis again, none more drugs struck, death on 21.02.2022. Time correlation to vaccination and none pre-existing conditions!) in a 77-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 000087A) for COVID-19 vaccination. . .Previously administered products included for Prophylactic vaccination: COMIRNATY on 14-Apr-2021 and COMIRNATY on 26-May-2021..Past adverse reactions to the above products included No adverse event with COMIRNATY; and Wegener's granulomatosis with COMIRNATY..Concurrent medical conditions included Wegener's granulomatosis.. .On 18-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 04-Jan-2022, the patient experienced GRANULOMATOSIS WITH POLYANGIITIS (After the 3rd vaccination on 18.12.2021, a strong outbreak of granulatosis again, none more drugs struck, death on 21.02.2022. Time correlation to vaccination and none pre-existing conditions!) (seriousness criterion death). The patient died on 21-Feb-2022. The reported cause of death was Wegener's granulomatosis. It is unknown if an autopsy was performed. . .Company comment: This regulatory case concerns a 77-year-old, female patient with no preexisting illness and past drug history of administration of two doses of Comirnaty (Pfizer/BioNTech COVID-19 mRNA vaccine) with medical history of Wegener´s granulomatosis after the second dose, who experienced the unexpected, serious (fatal) event of granulomatosis with polyangiitis (Wegener's granulomatosis). The event occurred 17 days after administration of the third dose of the Moderna mRNA-1273 vaccine. Two to three weeks after receiving the second dose of Comirnaty (Pfizer/BioNTech COVID-19 mRNA vaccine), the patient complained of cough and shortness of breath. She was admitted and was diagnosed with Granulomatosis with Polyangiitis, an immune disease of the lungs. She was discharged and therapy with cyclophosphamide was started. The patient recovered well by Dec2021. There were no more complaints and the patient's condition stabilized after a few months. The Chest X-ray and Computed Tomogram (CT) scan showed decreased changes in the lungs which showed good healing of the lung damage. However, 2 weeks after receiving the third dose of the Moderna mRNA-1273 vaccine, the patient again experienced 'discomfort cough' and shortness of breath. At the beginning of Feb2022, there was dramatic deterioration. There was further severe lung damage which was detected in the CT scan. Therapy was attempted with rituximab but this no longer occurred. The patient expired on 21Feb2022 (2 months, 3 days after vaccination with the third dose of the Moderna mRNA-1273 vaccine). The reported cause of death was 'Wegener's granulomatosis'. It is unknown if an autopsy was performed. The history of Wegener's granulomatosis after the second dose of Comirnaty, and past drug history of administration of two doses of Comirnaty (Pfizer/BioNTech COVID-19 mRNA vaccine) remain as confounders. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report.. .Most recent FOLLOW-UP

Case ID	WW Identifier	Narrative Complete
		information incorporated above includes:.On 30-Mar-2022: Upon internal review on 21-Apr-2022, non-significant correction was performed. The company comment was updated.
[redacted]	[redacted]	This case was initially received via European Medicines Agency (Reference number: [redacted] on 31-Mar-2022. The most recent information was received on 22-Apr-2022 and was forwarded to Moderna on 22-Apr-2022. .This regulatory authority case was reported by a physician and describes the occurrence of MYOCLONUS (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease), PRION DISEASE (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease), CONFUSIONAL STATE (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease), SOPOR (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease), DYSTONIA (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease), HALLUCINATION (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease), NERVOUS SYSTEM DISORDER (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease), DYSPHAGIA (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease), ATAXIA (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease), PSYCHOMOTOR HYPERACTIVITY (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease) and RESPIRATORY FAILURE (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease) in an 80-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000030A) for COVID-19 vaccination. . .Previously administered products included for Product used for unknown indication: COMIRNATY(BIONTECH MANUFACTURING GMBH) (J07BX03) on 23-Feb-2021 and COMIRNATY(BIONTECH MANUFACTURING GMBH) (J07BX03) on 13-Sep-2021..Past adverse reactions to the above products included No adverse event with COMIRNATY(BIONTECH MANUFACTURING GMBH) (J07BX03) and COMIRNATY(BIONTECH MANUFACTURING GMBH) (J07BX03).. ..On 18-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On 20-Jan-2022, the patient experienced MYOCLONUS (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease) (seriousness criterion death), PRION DISEASE (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease) (seriousness criterion death), CONFUSIONAL STATE (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease) (seriousness criterion death), SOPOR (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease) (seriousness criterion death), DYSTONIA (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease) (seriousness criterion death), HALLUCINATION (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease) (seriousness criterion death), NERVOUS SYSTEM DISORDER (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease) (seriousness criterion death), DYSPHAGIA (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease) (seriousness criterion death), ATAXIA (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease) (seriousness criterion death), PSYCHOMOTOR HYPERACTIVITY (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease) (seriousness criterion death) and

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		RESPIRATORY FAILURE (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease) (seriousness criterion death). The patient died on 09-Mar-2022. It is unknown if an autopsy was performed. . . .The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown.. .For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.. .No concomitant medication was reported..No treatment medication was reported...22/03/2022: Clinical report is attached by the signaller. The outcome of the autopsy will be attached, as soon as the report is available..Company Comment: This regulatory authority case concerns a 80-year-old male patient with no relevant medical history reported, who experienced the fatal unexpected serious events of Myoclonus, Prion disease, Confusional state, Sopor, Dystonia, Hallucination, Nervous system disorder, Dysphagia, Ataxia, Psychomotor hyperactivity and Respiratory failure which occurred 2 days after receiving a dose of mRNA-1273 vaccine. The patient died 50 days after vaccination. The reported cause of death was unknown. It is unknown if an autopsy was performed. Patient had received initial schedule of vaccination with COMIRNATY (interchange of vaccine products).The benefit-risk relationship of mRNA-1273 is not affected by this report. Events seriousness was assessed as per Regulatory Authority's report.. .Most recent FOLLOW-UP information incorporated above includes:.On 22-Apr-2022: Significant followup received on 22-APR-2022: Sender's comments updated..On 22-Apr-2022: Significant live followup received on 22-APR-2022: Event Prion disease added and all Events verbatim updated..On 06-May-2022: Follow-up received is NNI.
[redacted]		This regulatory authority case was reported by a physician and describes the occurrence of STAPHYLOCOCCAL SEPSIS (Sepsis MRSA), COAGULOPATHY (Acute coagulopathy), ENDOCARDITIS (Mitral valve endocarditis), THROMBOCYTOPENIA (Thrombopenia) and SEPTIC CEREBRAL EMBOLISM (Septic cerebral embolism) in a 49-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000136A) for COVID-19 vaccination. . .Previously administered products included for COVID-19 vaccination: COMIRNATY on 06-May-2021 and COMIRNATY on 02-Jun-2021..Past adverse reactions to the above products included No adverse event with COMIRNATY and COMIRNATY.. ..On 18-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 02-Feb-2022, the patient experienced STAPHYLOCOCCAL SEPSIS (Sepsis MRSA) (seriousness criteria death, hospitalization and life threatening), ENDOCARDITIS (Mitral valve endocarditis) (seriousness criteria death, hospitalization and life threatening) and SEPTIC CEREBRAL EMBOLISM (Septic cerebral embolism) (seriousness criteria death, hospitalization and life threatening). On 14-Feb-2022, the patient experienced THROMBOCYTOPENIA (Thrombopenia) (seriousness criteria death, hospitalization and life threatening). On an unknown date, the patient experienced COAGULOPATHY (Acute coagulopathy) (seriousness criteria death, hospitalization and life threatening). The patient died on 27-Feb-2022. The reported cause of death was disseminated intravascular coagulation dic. It is unknown if an autopsy was performed. . . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .No concomitant and treatment information was provided...This is a regulatory authority case concerning a 49-year-old, male patient with no relevant medical history, who experienced the unexpected serious (Fatal, Hospitalization and Life threatening) events of Staphylococcal sepsis, Coagulopathy, Endocarditis, Thrombocytopenia, Septic cerebral embolism. The events Staphylococcal sepsis, Endocarditis Septic cerebral embolism occurred 46 days after the third dose of mRNA-1273 COVID 19 Vaccine; While the event Thrombocytopenia occurred 58 days after the third dose of mRNA-1273 COVID 19 Vaccine. The event Coagulopathy occurred on an unknown date. Patient died 71 days after the third dose of mRNA-1273 COVID 19 Vaccine. The reported cause of death was disseminated intravascular coagulation. It was unknown if autopsy was performed. The benefit-risk relationship of mRNA-1273 COVID 19 Vaccine, is not affected by this report.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 05-Apr-2022 and was forwarded to Moderna on 05-Apr-2022. .This regulatory authority case was reported by a consumer and describes the occurrence of PULMONARY EMBOLISM (1 Astra vaccination, 2 Moderna vaccinations after 8 weeks of pulmonary embolism. None before Pre-existing illness!) in an adult male patient who received mRNA-1273 (Spikevax) (batch no. 214008) for COVID-19 vaccination. . .Previously administered products included for Prophylactic vaccination: Comirnaty BNT162b2 on 29-May-2021..Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2.. ..On 03-Aug-2021, the patient received dose of mRNA-1273 (Spikevax) (Intravenous) 1 dosage form. On 12-Oct-2021, the patient experienced PULMONARY EMBOLISM (1 Astra vaccination, 2 Moderna vaccinations after 8 weeks of pulmonary embolism. None before Pre-existing illness!) (seriousness criterion death). The patient died on 12-Oct-2021. The reported cause of death was Lung embolism. It is unknown if an autopsy

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		was performed. . . . . .No concomitant drug details were reported...Patient had no pre-existing illness..Dosage text was reported as '1 dose'...No treatment information was provided...Company Comment: This is a regulatory case of incorrect route of product administration (intravenous) for this adult (age not provided), male patient with past drug history of administration of a dose of Comirnaty (Pfizer/BioNTech COVID-19 mRNA vaccine) and a dose of the AstraZeneca COVID-19 vaccine, who experienced the unexpected, serious (fatal) AESI of pulmonary embolism. The event occurred approximately 2 months after administration of one dose of the Moderna mRNA-1273 vaccine. No further details were provided. The patient expired on 12Oct2021 (2 months, 9 days after vaccination). The reported cause of death was 'Lung embolism'. It is unknown if an autopsy was performed. The past drug history of administration of a dose of Comirnaty (Pfizer/BioNTech COVID-19 mRNA vaccine) and a dose of the AstraZeneca COVID-19 vaccine remains a confounder. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 05-Apr-2022 and was forwarded to Moderna on 05-Apr-2022. .This regulatory authority case was reported by a physician and describes the occurrence of CEREBRAL HAEMORRHAGE (Cerebral haemorrhage) in a 91-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 000125A) for COVID-19 vaccination. . .Previously administered products included for COVID-19 vaccination: Comirnaty BNT162b2 on 26-Mar-2021 and Comirnaty BNT162b2 on 07-Sep-2021..Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Comirnaty BNT162b2.. ..On 27-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 06-Mar-2022, the patient experienced CEREBRAL HAEMORRHAGE (Cerebral haemorrhage) (seriousness criteria death, hospitalization and life threatening). The patient died on 06-Mar-2022. It is unknown if an autopsy was performed. . . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .No concomitant medication reported..No treatment medication details reported...Company comment:.This regulatory authority case concerns a 91-year-old female patient, with no medical history reported, previously vaccinated with two doses of Comirnaty COVID-19 vaccine, who experienced the fatal AESI of Cerebral Haemorrhage (seriousness criteria death, hospitalization and life threatening), which occurred 1 month and 8 days after the third dose (reported as booster dose) of mRNA-1273. Cause of death was not provided, neither if an autopsy was performed. The patient died 1 month and 8 days after vaccination. The benefit-risk relationship of mRNA-1273 is not affected by this report.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 06-Apr-2022 and was forwarded to Moderna on 06-Apr-2022. .This regulatory authority case was reported by a consumer and describes the occurrence of ARRHYTHMIA (Arrhythmia) and CARDIAC ARREST (Arrest cardiac) in a 62-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000112A) for COVID-19 vaccination. . .The patient had no allergies..The patient's past medical history included ASS, Statin - approx. 2020 after stent use. .The patient's past medical history included Stent placement since an unknown date..Previously administered products included for Prophylactic vaccination: Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant])COVID-19 Vaccine AstraZeneca suspension for injectionCOVID-19 Vaccine AstraZeneca on 05-May-2021 and Comirnaty BNT162b2 on 16-Jul-2021..Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant])COVID-19 Vaccine AstraZeneca suspension for injectionCOVID-19 Vaccine AstraZeneca..Concurrent medical conditions included Type 2 diabetes mellitus, Hypertension and Autism spectrum disorder.. ..On 21-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 25-Jan-2022, the patient experienced ARRHYTHMIA (Arrhythmia) (seriousness criteria death and hospitalization) and CARDIAC ARREST (Arrest cardiac) (seriousness criteria death and hospitalization). The patient died on 07-Feb-2022. The reported cause of death was Arrest cardiac. It is unknown if an autopsy was performed. . . . . .Concomitant products: metformin for diabetes type II, 3 series of combination of the antihypertensive drugs Biso, HCT, Ramipril. Patient had high blood pressure cardiological check-up a few weeks earlier without findings and with very satisfactory result. It was reported date of birth 7-Aug-1959. Patient experienced sudden cardiac arrhythmias resulted in cardiac arrest. Patient had successful resuscitation (ROSC), but brain damage due to oxygen undersupply too large. Date of death was reported 7-Feb-2022 in the hospital, intensive care unit...CC: This regulatory case concerns a 62-year-old, male patient, with the relevant medical history of Type 2 diabetes mellitus – treated with metformin, stent placement, & Hypertension – treated with bisoprolol, who experienced the unexpected, fatal events of AESI Arrhythmia and Cardiac arrest 4 days after receiving his 3rd vaccination with mRNA-1273 COVID-19 vaccine. Reportedly, his 2-dose primary series of COVID-19 vaccines were with AstraZeneca & Pfizer. A few weeks before his 3rd vaccination, unremarkable cardiac findings were reported on his scheduled check-up. After receiving mRNA-1273 vaccine,

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		event arrhythmia suddenly occurred leading to cardiac arrest and to the patient's subsequent hospitalization. Patient was reportedly resuscitated and admitted to the intensive care unit for 13 days before expiring, possibly due to a massive brain damage. Cause of death was reported as cardiac arrest; however, limited information was provided on the clinical course, diagnostics, treatment details, and autopsy report for further medical review. Confounders to the fatal events of Arrhythmia and Cardiac arrest were his age, history of Type 2 diabetes mellitus, hypertension, stent placement, interchange of vaccine products, and the concomitant medications – metformin & bisoprolol. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness assessed per Regulatory Authority reporting.. .Most recent FOLLOW-UP information incorporated above includes:.On 13-Jun-2022: Follow-up information included no new information.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 06-Apr-2022 and was forwarded to Moderna on 06-Apr-2022. .This regulatory authority case was reported by a physician and describes the occurrence of DEATH (death: found dead in bed very pushed head) and THROMBOSIS (death: blood clot in the nose) in an 86-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 018J21A) for COVID-19 vaccination. . .Previously administered products included for Product used for unknown indication: COVID-19 VACCINE on 01-Nov-2020 and COVID-19 VACCINE on 01-Mar-2021..Past adverse reactions to the above products included No adverse event with COVID-19 VACCINE and COVID-19 VACCINE.. ..On 17-Mar-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, the patient experienced DEATH (death: found dead in bed very pushed head) (seriousness criterion death) and THROMBOSIS (death: blood clot in the nose) (seriousness criterion death). The patient died on 17-Mar-2022. The reported cause of death was Cerebral thrombosis. It is unknown if an autopsy was performed. . . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .No concomitant and treatment information was provided...Patient was found dead in bed very pushed head and had blood clot in the nose on 16-Mar-2022...Company Comment: This regulatory case concerns an 86-year-old, female patient with past drug history of administration of two doses of 'COVID-19 vaccine' (brands not specified), who experienced the unexpected, serious (fatal) AESI of thrombosis and the unexpected, serious (fatal) event of death. The events occurred 1 day after administration of an unspecified dose of the Moderna mRNA-1273 vaccine. The patient experienced a blood clot in the nose and was reported to have been found dead in bed with head 'very pushed/very stuffed'. No further details were provided. The patient expired on 17Mar2022. It is unknown if an autopsy was performed. However, the reported cause of death was 'Cerebral thrombosis'. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report.
[redacted]		This case was initially received via European Medicines Agency (Reference number: [redacted] on 08-Apr-2022. The most recent information was received on 19-Apr-2022 and was forwarded to Moderna on 19-Apr-2022. .This regulatory authority case was reported by a physician and describes the occurrence of HYPOXIA (death; hypoxia) in a 78-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 000060ABS) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. . .The patient's past medical history included CVA and COVID-19 on 08-Jan-2021..Previously administered products included for Product used for unknown indication: PFIZER BIONTECH COVID-19 VACCINE on 17-Apr-2021 and SPIKEVAX on 21-Dec-2021..Past adverse reactions to the above products included No adverse event with PFIZER BIONTECH COVID-19 VACCINE and SPIKEVAX..Concurrent medical conditions included Endometrial carcinoma..Concomitant products included CLOPIDOGREL, CANDESARTAN and ROSUVASTATIN CALCIUM (ROSUVASTATINE CF) for an unknown indication.. ..On 21-Mar-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 22-Mar-2022, the patient experienced PYREXIA (Fever: 38 to 40.5 degrees Celcius), HEADACHE (headache) and HYPOXIA (death; hypoxia) (seriousness criterion death). The patient died on 22-Mar-2022. The reported cause of death was hypoxia, there was a lot of foaming in the mouth. An autopsy was not performed. At the time of death, PYREXIA (Fever: 38 to 40.5 degrees Celcius) and HEADACHE (headache) had not resolved. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 08-Jan-2021, SARS-CoV-2 test positive: positive (Positive) Positive..On 22-Mar-2022, Pyrexia: 38 to 40.5 (High) Fever: 38 to 40.5 degrees Celsius.. . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .No treatment medications were reported...Company comment: This regulatory case concerns a 78-year-old female patient with relevant medical history of endometrial carcinoma, CVA and interchange of vaccine products, experienced the unexpected serious (fatal) event Hypoxia, one day after a dose of mRNA-1273 vaccine. It was reported that the patient had hypoxia, foaming in the mouth. Non-serious events of pyrexia and headache were experienced 14 hours post-vaccination. Clinical course leading to demise and treatment details were not provided in the case. An autopsy was not performed. The

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		patient also received one dose of Tozinameran as first COVID-19 vaccine approximately 8 months prior to the dose of mRNA-1273 vaccine. The elderly age of the patient could be a risk factor. Medical history of endometrial carcinoma, CVA could be confounders for the fatal outcome. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report.. .Most recent FOLLOW-UP information incorporated above includes:.On 19-Apr-2022: Significant follow up received - Updated Batch number
[redacted]		This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 12-Apr-2022. The most recent information was received on 12-May-2022 and was forwarded to Moderna on 18-May-2022. . This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, [redacted]. On 12-May-2022, follow-up information was received from a physician. On 24-Jul-2021, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 14-Aug-2021, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, body temperature before the vaccination: 36.4 degrees Celsius. On 02-Apr-2022, around 14:40, the patient received the 3rd vaccination with this vaccine. On 03-Apr-2022, around 21:00, the patient was presumed dead. It was a sudden death. On 04-Apr-2022, around 17:30, the patient did not come to a hospital for haemodialysis and was not connected when contacted. At 20:00, a family member visited and found the patient collapsed in the dressing room. The autopsy revealed that the estimated time of death was around 21:00 on 03-Apr-2022. CT scan was performed, and the cause of death was a suspected aortic dissection rupture. No autopsy was performed. The outcome of suspected aortic dissection rupture was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: The occurrence of the adverse event is not associated with concomitant drugs. The occurrence of the adverse event is associated with pathological factors of underlying diseases and complications. There is a temporal relationship, and the cause of death and the adverse event were related. Aortic dissection rupture can develop from underlying diseases. However, the temporal relationship with vaccination was noted, and it is considered that involvement cannot be ruled out. Follow-up received on 12-MAY-2022 Updated: Patient Information, Other Relevant History, Product Information, Narrative, Reporter Comments Company Comment: Sudden death after the administration of ELASOMERAN, but it may be affected by intercurrent event. Also, aortic dissection rupture occurred after the administration of ELASOMERAN, but it is possible that it may also be affected by concurrent condition.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 14-Apr-2022 and was forwarded to Moderna on 14-Apr-2022. .This regulatory authority case was reported by a physician and describes the occurrence of SUDDEN DEATH (Sudden death) in a 51-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 079F21A) for COVID-19 vaccination. . .Concomitant products included TOZINAMERAN (COMIRNATY) from 10-May-2021 to an unknown date for COVID-19 vaccination.. ..On 21-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. The patient died on 13-Jan-2022. The reported cause of death was cardiac arrest. It is unknown if an autopsy was performed. . . .For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.. .No treatment were reported...Company comment: This is a regulatory case concerning a 51 year-old, male patient with no reported medical history, who experienced the serious Fatal unexpected, event of sudden death, approximately 23 days after the mRNA-1273 vaccine, received as the third dose of COVID-19 vaccination schedule. The reported cause of death was cardiac arrest. It is unknown whether an autopsy was performed. Additionally, Interchange of vaccine products (vaccination with two doses of COVID-19 vaccine Tozinameran approximately 6 months prior) was noted in the case. No further clinical information was available for medical review. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
[redacted]		This case was initially received via European Medicines Agency (Reference number: [redacted] on 14-Apr-2022. The most recent information was received on 19-Apr-2022 and was forwarded to Moderna on 19-Apr-2022. .This regulatory authority case was reported by a consumer and describes the occurrence of HYPORESPONSIVE TO STIMULI (did not respond to anything and did not eat anymore), APATHY (apathetic) and HYPOPHAGIA (did not respond to anything and did not eat anymore) in an elderly female patient who received mRNA-1273 (Spikevax) (batch no. 216036) for COVID-19 vaccination. . .The patient's past medical history included Delirium (There was no family history) in 2020 and Surgery (There was no family history) in 2020..Previously administered products included for Product used for unknown indication: BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0,3ML on 14-Apr-2021 and COMIRNATY on 17-May-2021..Past adverse reactions to the above products included No adverse reaction with BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0,3ML and COMIRNATY..Concurrent medical conditions included Alzheimer's disease (There was no family

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		history) since 2013.. ..On 28-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, the patient experienced HYPORESPONSIVE TO STIMULI (did not respond to anything and did not eat anymore) (seriousness criterion death), APATHY (apathetic) (seriousness criterion death) and HYPOPHAGIA (did not respond to anything and did not eat anymore) (seriousness criterion death). The patient died on 07-Feb-2022. The reported cause of death was mortification. An autopsy was not performed. . . . . .Concomitant medication was not provided..Treatment information was not provided...Company Comment: This is a Regulatory Authority case concerning an elderly female patient, with relevant medical history of Alzheimer´s disease since 2013, delirium and surgery in 2020, who experienced the fatal events of Hyporesponsive to stimuli, Apathy and Hypophagia. The events occurred 4 days after a dose of mRNA-1273 vaccine, and patient died 1 month and 7 days after. Patient received 2 previous doses of Pfizer vaccine. It is unknown if an autopsy was performed, and the reported cause of death was Oral intake reduced. Medical history of Alzheimer´s disease, delirium, and surgery, remain confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 19-Apr-2022: Follow-up received wherein medical history, autopsy status and cause of death reported term updated.
[redacted]		This case was initially received via United Kingdom MHRA (Reference number: [redacted] on 15-Apr-2022. The most recent information was received on 19-May-2022 and was forwarded to Moderna on 19-May-2022. .This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (Died in sleep) in an 83-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 000076A) for COVID-19 vaccination. . .The patient's past medical history included Chemotherapy (for Squamous cell carcinoma) in 2010 and Radiotherapy (for Squamous cell carcinoma)..Previously administered products included for COVID-19 vaccination: SARS-COV-2 VIRUS, SARS-COV-2 VIRUS and SARS-COV-2 VIRUS..Past adverse reactions to the above products included No adverse drug reaction with SARS-COV-2 VIRUS, SARS-COV-2 VIRUS and SARS-COV-2 VIRUS..Concurrent medical conditions included Neoplasm (Recently had treatment for cancer, leukaemia or lymphoma (radiotherapy or chemotherapy)), Hypertension, Squamous cell carcinoma, Gastrointestinal neoplasm (Gastrointestinal stomach tumours) and Benign pleural neoplasm..Concomitant products included SENNA [SENNA ALEXANDRINA] for Constipation, DONEPEZIL, MEMANTINE and MIRTAZAPINE for Dementia, FLUOXETINE for Depression, ALLOPURINOL, ATENOLOL, LANSOPRAZOLE, SIMVASTATIN and PARACETAMOL for an unknown indication.. ..On 12-Apr-2022, the patient received fourth dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. Death occurred on 12-Apr-2022 The patient died on 12-Apr-2022. The cause of death was not reported. An autopsy was not performed. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 07-Mar-2022, SARS-CoV-2 test: no - negative covid-19 test (Negative) No - Negative COVID-19 test.. . .For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.. .Resident had previously had two COVID-19 vaccines and the first booster with no ill affects...It was reported that the resident was found to have passed away 2 hours following receiving the COVID-19 booster...Patient has not had symptoms associated with COVID-19. Patient has not tested positive for COVID-19 since having the vaccine..Patient was not enrolled in clinical trial...Report was not related to possible blood clots or low platelet counts. Report was not related to possible myocarditis or pericarditis...For investigations referred to coroner...No treatment information was provided...Company Comment: This regulatory case concerns an 83-year-old, female patient with relevant medical history of Squamous cell carcinoma status post chemotherapy and radiotherapy; Gastrointestinal stomach tumors; Hypertension; and past drug history of administration of three doses of COVID-19 vaccine (brand/s unspecified), who experienced the unexpected, serious (fatal and medically significant) event of death (died in sleep). The event occurred 2 hours after receiving the fourth (booster) dose of the mRNA-1273 vaccine. It was reported that the patient was found to have passed away 2 hours after receiving the COVID-19 booster dose. It was also reported that the patient had previously received two COVID-19 vaccines and the first booster (brand/s unspecified) with no reported side effects. Details of any relevant investigations or tests included referral to coroner. The cause of death was unexplained. No further details were provided and no autopsy was performed. The patient's age and relevant medical history mentioned above remain as confounders. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 19-May-2022: Follow-up information included medical history updated, cause of death, death date added and event outcome updated.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 18-Apr-2022 and was forwarded to Moderna on 18-Apr-2022. .This regulatory authority case was reported by a consumer and describes the occurrence of CARDIAC FAILURE (collapse, heart

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		failure) in an 86-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000114A) for COVID-19 vaccination. . .Patient concurrent medical history include long-term oxygen therapy with 2l for chronic heart suffer. as well as pulmonary hypertension with partial heart attack hypoxemia - diastolic heart failure severity I - COPD - permanent atrial fibrillation. .Previously administered products included for Prophylactic vaccination: Comirnaty BNT162b2 on 30-Jun-2021 and Comirnaty BNT162b2 on 22-Jul-2021..Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Comirnaty BNT162b2..Concurrent medical conditions included COPD, Hypertension, Tricuspid valve incompetence, Cardiac insufficiency, Decompensation cardiac, Bladder incontinence, Dyspnoea exertional, Hypoxaemia and Atrial fibrillation.. ..On 30-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 08-Jan-2022, the patient experienced CARDIAC FAILURE (collapse, heart failure) (seriousness criterion death). The patient died on 13-Jan-2022. The reported cause of death was Heart failure (NOS). It is unknown if an autopsy was performed. . . . . .No concomitant medications were provided by the reporter..It was reported as sudden unexpected collapse on the evening of 08 Jan 2022, resuscitation measures over 30 min long. Unstable briefing on the ITS. On 09 Jan 2022 independent breathing possible, awakens is responsive and without consequential damage. Phone calls without any abnormalities. Relocation to normal station on 11 Jan 2022. verstorben on the 2nd night on 13 Jan 22. Cancelled resuscitation measures..No treatment information was provided by the reporter...Company Comment:This regulatory authority case concerns an 86-year-old, male patient with relevant medical history of Hypertension, Tricuspid valve incompetence, Cardiac failure, and Atrial fibrillation who experienced the unexpected fatal adverse event of special interest of Cardiac failure. The event occurred 14 days after administration of mRNA-1273 taken as third dose of COVID-19 vaccination. Interchange of vaccine products is also noted in this case as patient received two doses of Comirnaty with the last dose taken approximately five months prior to administration of mRNA-1273 vaccine. Cardiopulmonary resuscitation was done after patient presented with sudden onset of loss of consciousness. Information about the concomitant medications, clinical course, diagnostic evaluation, and treatment details were not provided. The patient died five days after the event started. The cause of death was reported as Cardiac failure and it is unknown if an autopsy was performed. Patient's advanced age and medical history remain as confounders for the event and the fatal outcome. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per regulatory authority's report.
[redacted]		This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 18-Apr-2022. The most recent information was received on 25-Apr-2022 and was forwarded to Moderna on 28-Apr-2022. .This case was reported by a consumer via a medical representative. On 19-Apr-2022, follow-up information, reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, [redacted]). On 20-Apr-2022, follow-up information was received from a physician via a medical representative. On 26-Apr-2022, follow-up information was received from a physician. The vaccine recipient had no pre-existing medical conditions. On an unknown date, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 06-Feb-2022, in the morning, the patient received the 3rd vaccination with this vaccine. Pyrexia of 39 degrees Celsius developed. The patient took loxoprofen sodium hydrate, and the pyrexia resolved thereafter. On 08-Feb-2022, around 20:00, the patient was confirmed as alive. Thereafter, the patient experienced arrhythmia and died. On 09-Feb-2022, at 07:00, the patient was found dead in a left lateral recumbent position in the room. At 09:08 to 09:48, a necropsy was performed by the reporting physician. Postmortem CT showed no significant findings. Head CT: No organic intracerebral lesion such as subarachnoid haemorrhage was found. Chest CT: No appreciable findings. No coronary atherosclerosis was found. Abdominal CT: Hepatic steatosis and food residue in the stomach were found. The cause of death was determined to be arrhythmic death because the patient died suddenly, CT showed no appreciable findings including coronary arteries, and the condition of the heart before death was unknown because electrocardiogram was not performed in the medical checkups. Autopsy was not performed because the family members did not give their consent. The outcome of pyrexia was reported as resolved. The outcome of arrhythmia was reported as fatal. The outcome of hepatic steatosis was unknown. No follow-up investigation will be made. [Necropsy findings](Date of implementation:09-Feb-2022) ·The rectal temperature was 31 degrees Celsius with the room temperature of 17 degrees Celsius and the outside temperature of 7 degrees Celsius. ·Rigor mortis: jaw (++), neck (++), shoulders (++), elbows (++), wrists (++), fingers (++), groin (++), knees (++), ankle joints (++), toes (++). ·Dead spots: Half gone ·Cornea: Transparent ·Pupils: Precise circle ·Distention of carotid artery: None on the right, and mild on the left. ·Overflow points: 27 with the size of needlepoint and 4 with the size of needle head on the right and left eyelids

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		Reporter comments continuation: The occurrence of adverse events is not related to concomitant drugs. The occurrence of adverse events is not related to pathological factors of underlying diseases and complications. The relationship between the cause of death and adverse events is unknown. Since electrocardiogram was not performed in the medical examination, the condition of the heart is unknown. There is no lesion in the brain such as subarachnoid hemorrhage. CT was performed to show no remarkable findings, and thus the causality between this vaccine and death is considered unknown. Follow-up received on 25-APR-2022 Updated: Patient Information, Lab Data, Product Information, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
[redacted]		This case was received via European Medicines Agency (Reference number [redacted] on 22-Apr-2022 and was forwarded to Moderna on 22-Apr-2022. .This regulatory authority case was reported by a physician and describes the occurrence of ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction), MALAISE (Malaise), VENTRICULAR FIBRILLATION (Ventricular fibrillation) and DYSPNOEA (Dyspnoea) in a 72-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 21046) for COVID-19 vaccination. . .The patient's past medical history included Decompensated heart failure, Atrioventricular extrasystoles and Paralysis of diaphragm..Previously administered products included for COVID-19 vaccination: Comirnaty BNT162b2 on 26-May-2021 and Comirnaty BNT162b2 on 30-Jun-2021..Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Comirnaty BNT162b2..Concurrent medical conditions included Type II diabetes mellitus, Arterial hypertension and Guillain Barre syndrome in 2015.. ..On 07-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 17-Jan-2022, the patient experienced MALAISE (Malaise) (seriousness criteria death, hospitalization and life threatening) and DYSPNOEA (Dyspnoea) (seriousness criteria death, hospitalization and life threatening). On 18-Jan-2022, the patient experienced ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction) (seriousness criteria death, hospitalization, medically significant and life threatening) and VENTRICULAR FIBRILLATION (Ventricular fibrillation) (seriousness criteria death, hospitalization, medically significant and life threatening). The patient died on 18-Jan-2022. The reported cause of death was Acute myocardial infarction. An autopsy was not performed. . . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .No concomitant products were reported..No treatment drugs were reported..Company comment.This regulatory case concerns a 72-year-old female patient with medical history of Type II diabetes mellitus, Arterial hypertension, Decompensated heart failure, Atrioventricular extrasístoles, Paralysis of diaphragm, previously received 2 doses of Comirnaty, who experienced the serious (death, hospitalization, medically significant and life threatening) unexpected events of Acute Myocardial Infarction (AESI), Ventricular Fibrillation (AESI), Malaise and Dyspnoea. Malaise and dyspnoea occurred 10 days after the 3rd dose of mRNA-1273 vaccine and the following day the patient experienced Acute Myocardial Infarction and Ventricular Fibrillation. The reported cause of death was Acute myocardial infarction. An autopsy was not performed. The mentioned medical history and patient's age remains a confounder for the events since they could contribute to acute myocardial infarction. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
[redacted]		This case was initially received via European Medicines Agency (Reference number: [redacted] on 28-Apr-2022. The most recent information was received on 25-May-2022 and was forwarded to Moderna on 25-May-2022. .This regulatory authority case was reported by a physician and describes the occurrence of MESENTERIC VEIN THROMBOSIS (venous mesenteric thrombosis) and PORTAL VEIN THROMBOSIS (portal vein thrombosis) in a 62-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. . .The patient's past medical history included Diverticulitis (Family history reported as false.), Incision site bleeding (A: Since last week hemorrhoids, thrombosed hemorrhoid was found to be what was incidated by the GP. However, after a number of rectal blood loss suffered several times.) on 02-Apr-2021, Thrombosed hemorrhoids (NOS) (A: Since last week hemorrhoids, thrombosed hemorrhoid was found to be what was incidated by the GP. However, after a number of rectal blood loss suffered several times.) on 02-Apr-2021 and Rectal blood loss (after incision by general practitioner, several days) on 04-Apr-2021..Previously administered products included for Product used for unknown indication: COVID-19 VACCIN ASTRAZENECA INJVLST in 2021 and COVID-19 VACCIN ASTRAZENECA INJVLST in 2021..Past adverse reactions to the above products included No adverse event with COVID-19 VACCIN ASTRAZENECA INJVLST and COVID-19 VACCIN ASTRAZENECA INJVLST..Concurrent medical conditions included Type 2 diabetes mellitus (Family history reported as false.) and Hypertension (Family history reported as false.)..Concomitant products included METFORMIN (METFORMINE [METFORMIN]) and AMLODIPINE for an unknown indication..

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		..On 09-Apr-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 10-Apr-2022, the patient experienced MESENTERIC VEIN THROMBOSIS (venous mesenteric thrombosis) (seriousness criterion death) and PORTAL VEIN THROMBOSIS (portal vein thrombosis) (seriousness criterion death). 10-Apr-2022, the patient experienced THROMBOCYTOPENIA (Thrombocytopenia). The patient died on 11-Apr-2022. The reported cause of death was multiorgan failure in abdominal sepsis, catastrophic antiphospholipid syndrome (primary) and multiorgan failure in abdominal sepsis. An autopsy was not performed. At the time of death, THROMBOCYTOPENIA (Thrombocytopenia) had not resolved. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 10-Apr-2022, Blood alkaline phosphatase: 87 87..On 10-Apr-2022, Blood bilirubin: 80 80..On 10-Apr-2022, Blood fibrinogen: post operative: unmeasurable low post operative: unmeasurable low..On 10-Apr-2022, Blood test: ph 6.8, lactate 12.7, haptoglobulin <0.1, d-dimer pH 6.8, lactate 12.7, haptoglobulin <0.1, D-dimer >35, Fibrinogen <1.0. Significant number of values ??could no longer be determined due to hemolytic sample. Has not been redetermined because patient died in a short time...On 10-Apr-2022, C-reactive protein: 196 196..On 10-Apr-2022, Chest X-ray: abnormal X-thorax: poorly inspired, tube, central venous line and gastric probe lie well. No consolidations. High level right aperture...On 10-Apr-2022, Computerised tomogram abdomen: abnormal CT abdomen: diffuse venous mesenterial thrombosis with thrombosis vena porta and VMS and branches..On 10-Apr-2022, Culture: per operative ascites moisture: grow negative. per operative ascites moisture: grow negative. No blood cultures have taken place..On 10-Apr-2022, Fibrin D dimer: post operative: unmeasurably high post operative: unmeasurably high..On 10-Apr-2022, Haemoglobin: pre-ok: 9.4 post ok: 7.0 pre-OK: 9.4 Post OK: 7.0..On 10-Apr-2022, Liver function test: af87, ggt 97, asat and alat normal, ldh 300. AF87, GGT 97, ASAT and ALAT normal, LDH 300. pre- OK..On 10-Apr-2022, Platelet count: pre-ok:54 , post ok: 21 Pre-Ok:54 , Post OK: 21..On 10-Apr-2022, Platelet factor 4: pf 4 antibodies negative PF 4 antibodies negative..On 10-Apr-2022, SARS-CoV-2 test: negative (Negative) negative..On 10-Apr-2022, White blood cell count: pre ok : 5.9, post ok: 3 Pre OK : 5.9, post OK: 3..In April 2022, Antinuclear antibody: ana was positive. breakdown was negative. ANA was positive. Breakdown was negative...In April 2022, Antiphospholipid antibodies: antiphospholipid antibodies are detected. (lac pos Antiphospholipid antibodies are detected. (LAC pos, aCL neg, aB2GPI dub)...In April 2022, Platelet factor 4: negative, making vitt unlikely negative, making VITT unlikely.. . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .Treatment details was not reported by the reporter.. .Most recent FOLLOW-UP information incorporated above includes:.On 25-May-2022: Significant Follow up includes patient death cause added, Lab test details added and narrative was updated accordingly..On 25-May-2022: Translated document received on 31-May-2022 contains non significant information as the event verbatim and lab data term got updated from native to English..On 01-Jun-2022: Follow up received contains non significant information (event verbatim changed from thrombopenia to thrombocytopenia).
[redacted]		This regulatory authority case was reported by an other health care professional and describes the occurrence of COVID-19 (Critical Covid Pneumonia) and ACUTE MYOCARDIAL INFARCTION (Critical Covid Pneumonia, Acute Myocardial Infarction) in a 68-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. . .Co-suspect products included non-company products COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (ASTRAZENECA COVID-19 VACCINE) for an unknown indication and COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (ASTRAZENECA COVID-19 VACCINE) for an unknown indication.. .No Medical History information was reported.. .On 21-May-2021, the patient received dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (ASTRAZENECA COVID-19 VACCINE) (Intramuscular) 1 dosage form..On 30-Jul-2021, the patient received dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (ASTRAZENECA COVID-19 VACCINE) (Intramuscular) 1 dosage form..On 07-Jan-2022, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 20-Mar-2022, the patient experienced COVID-19 (Critical Covid Pneumonia) (seriousness criterion death) and ACUTE MYOCARDIAL INFARCTION (Critical Covid Pneumonia, Acute Myocardial Infarction) (seriousness criterion death). The reported cause of death was critical covid pneumonia and critical covid pneumonia, acute myocardial infarction. It is unknown if an autopsy was performed. . . .For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments.. .Concomitant product use was not provided by the reporter...No treatment information was provided...Company comment: This Fatal Regulatory Authority case concerns a 68-year-old, male patient, with no reported medical history, who experienced the unexpected, serious (death) AESI of COVID-19 (reported as critical COVID Pneumonia) and Acute myocardial infarction approximately 2 months and 13 days after receiving a dose of mRNA-1273 vaccine, considered as the third dose of the his COVID-19 vaccination schedule, as he previously received two doses of AstraZeneca's COVID-

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		19 vaccine, which remain as co-suspects. Date and cause of death were not reported. Autopsy report is not available. No further clinical information was provided for medical reviewing. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.
[redacted]		This case was initially received via United Kingdom MHRA (Reference number: [redacted]) on 01-May-2022. The most recent information was received on 10-May-2022 and was forwarded to Moderna on 10-May-2022. .This regulatory authority case was reported by a physician and describes the occurrence of DEATH (Death) in an 89-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 000075A) for COVID-19 vaccination. . .Patient was not on any medication. .Concurrent medical conditions included Dementia Alzheimer's type and Frailty..Concomitant products included TOZINAMERAN (COMIRNATY) from 27-Sep-2021 to 27-Sep-2021 and NITROFURANTOIN from 08-Apr-2022 to an unknown date for an unknown indication.. ..On 26-Apr-2022, the patient received fourth dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. Death occurred on 27-Apr-2022 The patient died on 27-Apr-2022. The reported cause of death was Frailty and Dementia Alzheimer's type. It is unknown if an autopsy was performed. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On an unknown date, SARS-CoV-2 test: not infected (Negative) Not infected.. . .For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.. .Patient had no symptoms associated with COVID-19. Not had a COVID-19 test. ..Patient had the vaccine on Tuesday morning and was found in her bed on Wednesday morning. No pulse was present. Death was referred to the coroner..Patient had not tested positive for COVID-19 since having the vaccine. Patient was not enrolled in clinical trial..The report was not related to possible blood clots or low platelet counts..The report was not related to possible myocarditis or pericarditis..No treatment information was provided..The reported cause of death was frailty of old age..Reporter do not have copy of the post-mortem report...Company Comment: This regulatory authority case of Interchange of vaccine products concerning an 89-year-old, female patient with concurrent medical conditions of Dementia Alzheimer's type and Frailty and concomitant medication with Nitrofurantoin, previously vaccinated with a dose of COVID-19 vaccine Comirnaty (dose number not specified; no adverse event reported) who experienced the unexpected serious event of unexplained Death which occurred 1 day after a dose of mRNA-1273 vaccine, dose 4 in vaccine series. The next morning after vaccination, patient was found in her bed without pulse. Reported cause of fatality was Death unexplained. An autopsy was performed and the autopsy-determined causes of death were Frailty and Dementia Alzheimer's type. COVID-19 virus test was negative. At the time of the report, very limited information has been provided about the patient and about the event leading to the fatal outcome. The patient's elderly age, concurrent medical conditions, and concomitant medication with Nitrofurantoin remain as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 10-May-2022: Patient age updated. Cause of death added. Relevant medical history and concurrent conditions added. Other Concomitant Medications added. The adverse event MedDRA terminology was updated to Death unexplained. Event stop date and Lab Data were added. Action taken updated to Not applicable.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted]) on 02-May-2022 and was forwarded to Moderna on 02-May-2022. .This regulatory authority case was reported by a consumer and describes the occurrence of ECZEMA (Allergic reaction: acute swelling of the face (especially lips) and strong itching on both sides of the hand. On the Hands, the patient developed eczema, which together with itching until death), HYPERSENSITIVITY (Allergic reaction: acute swelling of the face (especially lips) and strong itching on both sides of the hand. On the Hands, the patient developed eczema, which together with itching until death), PULMONARY MASS (Multiple ossifications in both lungs, especially near the pleura and in the lower lobes.), PRURITUS (Allergic reaction: acute swelling of the face (especially lips) and strong itching on both sides of the hand. On the Hands, the patient developed eczema, which together with itching until death) and PULMONARY HAEMORRHAGE (Pulmonary hemorrhage, diffuse alveolar hemorrhage.) in a 40-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. . .Previously administered products included for Prophylactic vaccination: Comirnaty BNT162b2 and Comirnaty BNT162b2..Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Comirnaty BNT162b2..Concurrent medical conditions included Breast tumor benign in 2020, Hay fever, Goiter, Neurodermatitis and Lung hemorrhage.. ..On 19-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 3 dosage form. On 19-Jan-2022, the patient experienced ECZEMA (Allergic reaction: acute swelling of the face (especially lips) and strong itching on both sides of the hand. On the Hands, the patient developed eczema, which together with itching until death) (seriousness criterion medically significant), HYPERSENSITIVITY (Allergic reaction: acute swelling of the face (especially lips) and

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		strong itching on both sides of the hand. On the Hands, the patient developed eczema, which together with itching until death) (seriousness criterion medically significant) and PRURITUS (Allergic reaction: acute swelling of the face (especially lips) and strong itching on both sides of the hand. On the Hands, the patient developed eczema, which together with itching until death) (seriousness criterion medically significant). On 24-Feb-2022, the patient experienced PULMONARY MASS (Multiple ossifications in both lungs, especially near the pleura and in the lower lobes.) (seriousness criterion death) and PULMONARY HAEMORRHAGE (Pulmonary hemorrhage, diffuse alveolar hemorrhage.) (seriousness criterion death). The patient died on 24-Feb-2022. The reported cause of death was Lung hemorrhage. An autopsy was performed. At the time of death, ECZEMA (Allergic reaction: acute swelling of the face (especially lips) and strong itching on both sides of the hand. On the Hands, the patient developed eczema, which together with itching until death), HYPERSENSITIVITY (Allergic reaction: acute swelling of the face (especially lips) and strong itching on both sides of the hand. On the Hands, the patient developed eczema, which together with itching until death) and PRURITUS (Allergic reaction: acute swelling of the face (especially lips) and strong itching on both sides of the hand. On the Hands, the patient developed eczema, which together with itching until death) was resolving. . . . . .Concomitant and treatment drug details were not rpeorted..It was reported that, the autopsy revealed diffuse alveolar hemorrhage as the main finding. Multiple ossification in both lungs, in particular close to the pleura and lower lobes, were detectable as a conspicuous side finding with no disease value. Other serious organic changes that could have led to death were not detectable...Company comment: This regulatory case concerns a 40-year-old female patient with relevant medical history of Hay fever and Neurodermatitis, and interchange of vaccine products, who experienced the unexpected serious (death) events Pulmonary mass and Pulmonary haemorrhage, and unexpected serious (medically significant) events Eczema, Pruritus and Hypersensitivity, on same day after a dose of mRNA-1273. The patient experienced acute swelling of the face (especially the lips) and severe Itching on both palms. The patient developed eczema on her hands, which together with the itch continued till death. An autopsy revealed diffuse alveolar haemorrhage as the main finding. Multiple ossification in both lungs, close to the pleura and lower lobes, were detectable as a conspicuous side finding with no disease value. Other serious organic changes that could have led to death were not detectable. Medical history of Hay fever and Neurodermatitis could be confounders for the events Pulmonary haemorrhage, Eczema, Pruritus and Hypersensitivity. Prior to Moderna Vaccine, the patient had taken two doses of Comirnaty BNT162b2 Covid-19 vaccine (dates not specified). The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report.. .Most recent FOLLOW-UP information incorporated above includes:.On 02-May-2022: Translation received-Event verbatim updated for PT-Pulmonary mass..On 06-May-2022: Non significant follow up received on 06-May-2022. Events verbatim updated.
[redacted]		This case was initially received via European Medicines Agency (Reference number: [redacted] on 02-May-2022. The most recent information was received on 09-May-2022 and was forwarded to Moderna on 09-May-2022. .This regulatory authority case was reported by a physician and describes the occurrence of DYSPNOEA (at 30.03 to which pt was sent to the EH with increasing dyspnea complaints.), GRANULOMATOSIS WITH POLYANGIITIS (exac GPA/Wegener), HAEMOPTYSIS (Hemoptysis) and CONDITION AGGRAVATED (exac GPA/Wegener) in an 86-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. . .The patient's past medical history included Anterior myocardial infarction (Family History: false), Granulomatosis with polyangiitis (Family History: false), COPD exacerbation (Family History: false) and Multiple vessel coronary artery disease (Family History: false)..Previously administered products included for Product used for unknown indication: COVID-19 VACCINE on 01-Jan-2021, COVID-19 VACCINE on 19-Feb-2021 and COVID-19 VACCINE on 19-Nov-2021..Past adverse reactions to the above products included No adverse event with COVID-19 VACCINE, COVID-19 VACCINE and COVID-19 VACCINE..Concomitant products included BUDESONIDE, FORMOTEROL FUMARATE (BUDESONIDE AND FORMOTEROL) for COPD, OMEPRAZOLE (OMEPRAZOL [OMEPRAZOLE]), CARBASALATE CALCIUM (CARBASALAATCALCIUM), HYDROCHLOORTHIAZIDE, LOSARTAN POTASSIUM (LOSARTAN TEVA), AMLODIPINE, ATORVASTATIN (ATORVASTATINE [ATORVASTATIN]), BISOPROLOL FUMARATE, AZITHROMYCIN (AZITROMYCINE) and METFORMIN HYDROCHLORIDE (METFORMIN [METFORMIN HYDROCHLORIDE]) for an unknown indication.. ..On 11-Mar-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 12-Mar-2022, the patient experienced COUGH (Since booster is increasingly suffering from dyspnea with progressive cough symptoms.) and DYSPNOEA (Since booster is increasingly suffering from dyspnea with progressive cough symptoms.). On 18-Mar-2022, the patient experienced COUGH (/Presented at

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		18.03 in HA with increased cough and dyspnea. Wishes AB then. No AB received) and DYSPNOEA (Presented at 18.03 in HA with increased cough and dyspnea. Wishes AB then. No AB received). On 30-Mar-2022, the patient experienced DYSPNOEA (at 30.03 to which pt was sent to the EH with increasing dyspnea complaints.) (seriousness criterion hospitalization). On 31-Mar-2022, the patient experienced HAEMOPTYSIS (Hemoptysis) (seriousness criterion death). On an unknown date, the patient experienced GRANULOMATOSIS WITH POLYANGIITIS (exac GPA/Wegener) (seriousness criterion death) and CONDITION AGGRAVATED (exac GPA/Wegener) (seriousness criterion death). The patient died on 31-Mar-2022. The reported cause of death was pulmonary manifestation gpa/wegener, pulmonary manifestation gpa/wegener, acute pulmonary hemorrhage (primary), Hemoptysis and pulmonary manifestation gpa/wegener. It is unknown if an autopsy was performed. At the time of death, DYSPNOEA (at 30.03 to which pt was sent to the EH with increasing dyspnea complaints.), COUGH (/Presented at 18.03 in HA with increased cough and dyspnea. Wishes AB then. No AB received), COUGH (Since booster is increasingly suffering from dyspnea with progressive cough symptoms.), DYSPNOEA (Presented at 18.03 in HA with increased cough and dyspnea. Wishes AB then. No AB received) and DYSPNOEA (Since booster is increasingly suffering from dyspnea with progressive cough symptoms.) had not resolved. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 30-Mar-2021, Blood test: anemia anemia..On 30-Mar-2021, Renal function test: renal impairment renal impairment..On 30-Mar-2021, Urine analysis: erythrocyturie erythrocyturie..On 30-Mar-2022, Antineutrophil cytoplasmic antibody: positive (Positive) ANCA/PR3 strong positive..On 31-Mar-2022, Chest X-ray: known consolidations in both top fields have been Known consolidations in both top fields have been visible again compared to 1 day before. No indication of pneumothorax. Slim vessel drawing, mediastinum and cor show no indication of overfilling...On 31-Mar-2022, Laboratory test: used: eries 2068, leu 178, bacteria negative, ery USED: eries 2068, Leu 178, bacteria negative, ery cylinders absent. and creatinine 115, egfr 37, na 129, k 4.2, crp 198, h creatinine 115, eGFR 37, Na 129, K 4.2, CRP 198, Hb 4.7, MCV 84, Leu 12.9, Tr 247, PR3 >177... . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .No Treatment medications were provided..CC: This regulatory authority case concerns an 86 year old female patient with relevant medical history of Granulomatosis with polyangiitis, Myocardial infarction, Chronic obstructive pulmonary disease and Coronary artery disease, previously vaccinated with three doses of Covid 19 vaccine type /brand not reported with no reported adverse events , who experienced the Serious(fatal), unexpected events of DYSPNOEA (at 30.03 to which pt was sent to the EH with increasing dyspnea complaints.), GRANULOMATOSIS WITH POLYANGIITIS (exac GPA/Wegener), HAEMOPTYSIS (Hemoptysis) and CONDITION AGGRAVATED (exac GPA/Wegener), which occurred 19-20 days post vaccination with an unknown dose number of mRNA-1273 vaccine. This patient was reported to have died 20 days post vaccination and the reported cause of death were as follows : Pulmonary Granulomatosis , hemoptysis , Pulmonary hemorrhage , Disease Aggravation and Pulmonary manifestation of Granulomatosis Polyangitis /Wegener's . It is unknown if an autopsy was done. Laboratories reported : Antineutrophil cytoplasmi ANCA/PR3 strong positive Blood test;anemia Renal function test: renal impairment; Urinalysis ;erythrocyturie; Chest x-ray: Chest X-ray;31-MAR-2022;Known consolidations in both top fields have been;Known consolidations in both top fields have been visible again compared to 1 day before. No indication of pneumothorax. Slim vessel drawing, mediastinum and cor show no indication of overfilling. The details of the hospitalization and treatment information were not reported. The medical history ofGranulomatosis with polyangiitis, Myocardial infarction, Chronic obstructive pulmonary disease and Coronary artery disease, and the age of this patient plus the history of previous vaccination for 3 doses of Covid 19 vaccine are considered as confounders for all of the events. The benefit -risk relationship of mRNA -1273 is not affected by this report. Events' seriousness assessed as per RA. .On 31-Mar-2021, the patient experienced GRANULOMATOSIS WITH POLYANGIITIS (exac GPA/Wegener) (seriousness criterion death).. .Most recent FOLLOW-UP information incorporated above includes:.On 09-May-2022: Significant follow up: Concurrent conditions, lab data, event onset date and concomitant medication details added..On 09-May-2022: Translated document attached on12-MAY-2022. Lab data free text was translated and event verbatim was translated.
[redacted]		This case was received via European Medicines Agency (Reference number:[redacted] on 04-May-2022 and was forwarded to Moderna on 04-May-2022. .This regulatory authority case was reported by a consumer and describes the occurrence of PULMONARY EMBOLISM (pulmonary embolism) in a 38-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 000114A) for COVID-19 vaccination. . .Previously administered products included for Prophylactic vaccination: COVID-19 Vaccine Janssen Injektionssuspension COVID-19 Vaccine JanssenCOVID-19-Impfstoff Ad26.COV2-S on 03-Jun-2021 and Spikevax COVID-19 mRNA

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		Vaccine (nucleoside modified)COVID-19 Vaccine Moderna dispersion for injectionSpykeVax on 06-Jan-2022..Past adverse reactions to the above products included Leg venous thrombosis with COVID-19 Vaccine Janssen Injektionssuspension COVID-19 Vaccine JanssenCOVID-19-Impfstoff Ad26.COV2-S; and No adverse event with Spikevax COVID-19 mRNA Vaccine (nucleoside modified)COVID-19 Vaccine Moderna dispersion for injectionSpykeVax.. ..On 05-Apr-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 3 dosage form. On 11-Apr-2022, the patient experienced PULMONARY EMBOLISM (pulmonary embolism) (seriousness criterion death). The patient died on 11-Apr-2022. The reported cause of death was Pulmonary embolism. It is unknown if an autopsy was performed. . . . . .Concomitant medication was not provided...Treatment information was not provided...Company comment. This fatal regulatory case concerns a 38 – year – old, female patient with relevant medical history of leg venous thrombosis, who experienced the unexpected, serious AESI of pulmonary embolism. The event occurred 6 days after the administration of a dose of mRNA-1273 vaccine; the patient previously had one dose of Janssen COVID – 19 vaccines 10 months prior (revaccination with different COVID – 19 vaccine could be considered) and a dose of mRNA – 1273 vaccine 3 months prior. The report stated that the patient experienced pulmonary embolism with a fatal outcome. The reported cause of death was pulmonary embolism. It is unknown if an autopsy was performed. No further details were provided for medical review. Patient's medical history of leg venous thrombosis could be confounder for pulmonary embolism. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 04-May-2022: Translation received on 05-MAY-2022 included non significant information. Event verbatim updated.
[redacted]	[redacted]	This case was received via European Medicines Agency (Reference number: [redacted]) on 04-May-2022 and was forwarded to Moderna on 04-May-2022. .This regulatory authority case was reported by a pharmacist and describes the occurrence of COVID-19 PNEUMONIA (COVID-19 pneumonitis) and VACCINATION FAILURE (Vaccination failure) in a 78-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. . .Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 vaccination.. .The patient's past medical history included Cardiac hypertrophy, Enlarged clitoris, Failure respiratory, Breast lump NOS, Obesity, Dyslipidaemia, Hysterectomy and Vulvectomy..Concurrent medical conditions included Non-insulin-dependent diabetes mellitus, Arthritis rheumatoid, Biliary atresia and Hypertension arterial..Concomitant products included FOLIC ACID (ACIDE FOLIQUE), SALBUTAMOL, BISOPROLOL FUMARATE (BISOPROLOL LPH), ATORVASTATIN CALCIUM (ATORVASTATINE EG), METHOTREXATE, PREDNISOLONE METASULFOBENZOATE SODIUM (SOLUPRED ORO) and PROCAINE HYDROCHLORIDE (CHLORHYDRATE DE PROCAINE) for an unknown indication.. .On 27-Apr-2021, the patient received dose of TOZINAMERAN (COMIRNATY) (Intramuscular) .3 milliliter every six weeks..On 08-Jun-2021, received dose of TOZINAMERAN (COMIRNATY) (Intramuscular) dosage was changed to .3 milliliter..On 04-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On an unknown date, the patient experienced COVID-19 PNEUMONIA (COVID-19 pneumonitis) (seriousness criterion death) and VACCINATION FAILURE (Vaccination failure) (seriousness criterion death). The patient died on 24-Mar-2022. The reported cause of death was multiple organ failure. An autopsy was not performed. . . .For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.. .Suspect dosage text was reported as R1..No treatment details were reported..Company comment:This regulatory authority case concerns a 78 year old female patient with underlying medical history of Cardiac hypertrophy, prior surgery of Hysterectomy, Vulvectomy, Type 2 Diabetes Mellitus, Respiratory Failure, Hypertension, Obesity and Dyslipidaemia, who experienced the unexpected, serious(Fatal) adverse event of special interest of COVID-19 Pneumonia. The event occurred at an unspecified date after receiving a dose of mRNA1273. Vaccination failure was also reported in the case. It should be noted that the patient received 2 doses of different COVID-19 vaccine (Comirnaty) approximately 5 months and 26 days prior to the latest dose of mRNA1273 (inappropriate schedule of vaccine administered). The patient expired on 24-Mar-2022 and the cause of death reported was multiple organ failure .The clinical course that lead to the demise of the patient and treatment details were not provided in the case. The patient's advanced age and underlying medical history of cardiac hypertrophy, prior surgeries, Type 2 diabetes mellitus, respiratory failure, hypertension, obesity and dyslipidaemia may be considered as risk factors for the event of COVID-19 pneumonia. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness assessed as per Regulatory Authority.
[redacted]		This regulatory authority case was reported by an other health care professional and describes the occurrence of HEADACHE (Headache), NAUSEA (Nausea) and VOMITING (Vomit) in a 51-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19

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		vaccination. . .Previously administered products included for Product used for unknown indication: BNT (Dose 1 vaccines (BNT).) on 19-Oct-2021 and BNT (Dose 2 vaccines (BNT).) on 27-Nov-2021..Past adverse reactions to the above products included No adverse event with BNT and BNT.. ..On 06-Apr-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 07-Apr-2022, the patient experienced HEADACHE (Headache) (seriousness criterion death), NAUSEA (Nausea) (seriousness criterion death) and VOMITING (Vomit) (seriousness criterion death). The patient died on 07-Apr-2022. The reported cause of death was spontaneous intracranial hemorrhage. An autopsy was performed. . . .For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.. .Patient had no allergy history(Medication)food allergy..No concomitant medication details was provided...Company Comment: On 11-April 2022 it was reported that after received the covid-19 vaccine patient had headache and vomiting in the midnight. His family found his body cold with no vital signs around 5:00pm of April 7, 2022. We called the patient husband's mobile phone and asked about how was the patient doing after vaccination. The husband said that she felt ok after vaccination on the afternoon but began to have headache and vomiting after midnight. The patient's daughter thought it was one of the general uncomfortable symptoms of inoculation after online searches. The patient also said herself that she didn't need to go to the hospital, so they didn't visit any doctor for medical adviceAt about 5:00 pm on April 7, 2022, the daughter touched the body of the patient and find that the body was cold with no vital signs, called for case assistance, dialed 119, and requested the police station for assistance. We told the husband about the remedy application procedure, and the husband said he understood. When asked about the time of the patient's autopsy, the husband said that the forensic doctor was expected to perform the autopsy at about 4:00 pm today. Patient did not seek medical advice. .At about 5:00 pm on April 7, 2022, the patient was found dead and not sent to hospital. On April 11, 2022 A judicial autopsy was arranged to find out the cause of death.
[redacted]		This case was initially received via European Medicines Agency (Reference number: [redacted] on 05-May-2022. The most recent information was received on 01-Jun-2022 and was forwarded to Moderna on 01-Jun-2022. .This regulatory authority case was reported by a consumer and describes the occurrence of CARDIAC FAILURE ACUTE (Acute heart failure), ENDOCARDITIS (histological evidence of myocarditis and endocarditis), BRAIN OEDEMA (Brain edema) and MYOCARDITIS (histological evidence of myocarditis and endocarditis) in a 51-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. . .The patient's past medical history included Cardiac hypertrophy and Nicotine abuse..Previously administered products included for Prophylactic vaccination: Corona-Vaccine COVID-19..Past adverse reactions to the above products included No adverse event with Corona-Vaccine COVID-19.. ..On 07-Jul-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 2 dosage form. On 08-Jul-2021, the patient experienced INFLUENZA LIKE ILLNESS (flu-like symptoms). On 10-Jul-2021, the patient experienced CARDIAC FAILURE ACUTE (Acute heart failure) (seriousness criteria death and hospitalization), ENDOCARDITIS (histological evidence of myocarditis and endocarditis) (seriousness criterion death), BRAIN OEDEMA (Brain edema) (seriousness criterion hospitalization) and MYOCARDITIS (histological evidence of myocarditis and endocarditis) (seriousness criterion death). The patient was treated with IBUPROFEN on 09-Jul-2021 at a dose of 400 milligram once a day. The patient died on 10-Jul-2021. The reported cause of death was Acute heart failure. An autopsy was performed. The autopsy-determined cause of death was Acute heart failure, Brain edema, focal inflammatory infiltrates and necrosis and Aortic arteriosclerosis. At the time of death, INFLUENZA LIKE ILLNESS (flu-like symptoms) was resolving and BRAIN OEDEMA (Brain edema) outcome was unknown. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On an unknown date, Body temperature: 37.3°c temp. 37.3°C.. . . . .All information was based on police investigations After the 1st vaccination, patient had none symptoms or complaints and following day of the 2nd vaccination patient had flu-like symptoms. Patient found death on 10 Jul, died around 8am .Previous illnesses Cardiac hypertrophy, nicotine abuse, no other previous illnesses, no medication / death investigation, after 1st vaccination no symptoms/complaints on the day after the 2nd vaccination "flu-like symptoms", temperature 37.3°C, none medication, rested, on 09.07.2021 continued flu-like symptoms , early and 1x ibuprofen 400 mg taken in the evening, on 10.07. dead around 8am found. ..Company Comment: This is a Regulatory Authority case concerning a 51-year-old male patient, with medical history of Cardiac hypertrophy, previously vaccinated with a dose of Corona-Vaccine COVID-19, who experienced the fatal unexpected events of Cardiac failure acute (AESI), Myocarditis (AESI), Endocarditis and the serious unexpected events of Brain oedema. The same day of the vaccination with the second dose of the mRNA-1273 vaccine, the patient presents flu-like symptoms, temperature 37.3°C and was medicated with ibuprofen 400 mg. Three days after

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		vaccination, the patient was hospitalized due to of Cardiac failure acute and Brain oedema. Additionally, on the same day Myocarditis and Endocarditis were diagnosed (histological diagnosis) and the patient died. An autopsy was performed, and the reported causes of death were Acute heart failure, Brain edema, Myocarditis and Aortic arteriosclerosis. No further information on clinical course, treatments performed was disclosed. Limited information was provided at this time. The medical history of Cardiac hypertrophy remains as a contributor for the event of Cardiac failure acute. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event term, onset date and seriousness were captured as provided by the Regulatory Authority.. .Most recent FOLLOW-UP information incorporated above includes:.On 16-May-2022: Follow-up received contains no new information (NNI)..On 24-May-2022: Non-Significant Follow-up..On 01-Jun-2022: Follow-up received include : Autopsy result (Cardiac failure acute, Brain oedema , Aortic arteriosclerosis, Myocarditis)added, Event (Cardiac failure acute, Brain oedema) added, Event Verbatim (Endocarditis, Myocarditis) added.
[redacted]		This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted]) on 02-May-2022. The most recent information was received on 01-Jun-2022 and was forwarded to Moderna on 08-Jun-2022. .This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, [redacted]). On an unknown date, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, body temperature before the vaccination: 36.4 degrees Celsius. On 25-Apr-2022, at 15:50, the patient received the 3rd vaccination with this vaccine. On 26-Apr-2022, at 07:56, pyrexia of 39.3 degrees Celsius developed. The patient took one tablet of acetaminophen 300 mg. At 13:30, body temperature was 39.9 degrees Celsius, and malaise and chills were noted. The patient was unable to sit up for himself and assisted. The patient took one tablet of acetaminophen 300 mg. At 14:18, the patient wanted to urinate but had incontinence. At 14:55, a nurse bought water on behalf of the patient. The patient was unable to fill out the form and said thank you. At 17:47, the patient lay down prone in bed. The patient experienced apnoea, and cardiopulmonary resuscitation was performed. Thereafter, the patient died. The outcome of pyrexia, malaise, chills, inability to sit up for himself, and incontinence was unknown. The outcome of apnoea was reported as fatal. Follow-up investigation will be made. Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
[redacted]		This regulatory authority case was reported by an other health care professional and describes the occurrence of PYREXIA (Fever) and VACCINATION SITE PAIN (Pain at inoculation site) in a 34-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. . .Previously administered products included for Product used for unknown indication: (AZ) vaccine (Dose 1) on 27-Jul-2021, (AZ) vaccine (patient started to have diarrhea and fever at noon of 28-Jul-2021) on 27-Jul-2021, (AZ) vaccine (Dose 2 and symptoms relieved 1-2 weeks later) on 21-Oct-2021..Past adverse reactions to the above products included Diarrhea with (AZ) vaccine; Fever with (AZ) vaccine; and Hand pain with (AZ) vaccine.. ..On 16-Apr-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 17-Apr-2022, the patient experienced PYREXIA (Fever) (seriousness criterion death) and VACCINATION SITE PAIN (Pain at inoculation site) (seriousness criterion death). The patient died on 19-Apr-2022. The cause of death was not reported. An autopsy was performed. . . .For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.. .The patient received first dose of AZ vaccine on 27-Jul-2021. He started to have diarrhea and fever at noon of 28-Jul-2021. He took antipyretic medicine, and the symptoms relieved a few days later. The patient received second dose of AZ on 21-Oct-2021. He had left hand soreness and symptoms relieved 1-2 weeks later. The patient received third dose of Moderna vaccine on 16-Apr-2022 and started to have a fever and sore left hand at about 3:40 am on 17-Apr-2022. The patient wife said she could not get in touch with the patient at 10:00 pm on 17-Apr-2022 or 12:00 am on 18-Apr-2022. On 18-Apr-2022, the patient mother came to the place where he lived by himself and discovered that he was dead. She called an ambulance and the paramedics said no need to be sent to the hospital since the patient was obviously gone. At 4:30 pm of 18-Apr-2022, the forensic doctor arrived at the site. The wife said that she would not choose autopsy. Follow up was performed, initially determined cause of death: unknown. The autopsy performed on 19-Apr-2022, indicated that incomplete digestion of food was found in the stomach of the dead, and the time of death should be within two hours after dinner. According to the family member, the patient had dinner at 8:00 pm on 17-Apr-2022, and the time of death may have been before 11:00 pm of 17-Apr-2022. But the time of death on the certificate is the time he was found dead: 10:18 of 18-Apr-2022. The patient was a freelancer, and his history of chronic diseases need to be confirmed by his wife...The Worldwide UID was reported as

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		[redacted].Company Comment : This fatal regulatory authority case concerns a 34-year-old male patient, with medical history of chronic diseases (not specified), who experienced the serious (due to death) unexpected events of PYREXIA and VACCINATION SITE PAIN, on the following day of the dose of mRNA-1273 vaccine, considered as the third dose of the vaccination schedule, and died on the same day that the events occurred. Previously he received 2 doses of AstraZeneca vaccine. The reported cause of death was unknown. The autopsy revealed that he died 2 hours after having dinner on the following day of the vaccination. The history of chronic diseases remains as a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
[redacted]		This regulatory authority case was reported by an other health care professional and describes the occurrence of HEADACHE (Headache) and MUSCULAR WEAKNESS (Weakness of limbs) in a 62-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. . .Previously administered products included for Product used for unknown indication: AZ (Patient received Dose 1 (AZ) on November 8 and 2021.) on 08-Nov-2021..Past adverse reactions to the above products included No adverse event with AZ..Concurrent medical conditions included Pulmonary fibrosis (Chronic disease: Pulmonary fibrosis).. .On 12-Jan-2022, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form..On 15-Apr-2022, received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 21-Apr-2022, the patient experienced HEADACHE (Headache) (seriousness criterion death) and MUSCULAR WEAKNESS (Weakness of limbs) (seriousness criterion death). The patient died on 21-Apr-2022. The reported cause of death was Headache and Weakness of limbs. It is unknown if an autopsy was performed. . . .For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.. .No concomitant product use was provided by the reporter..The daughter of the patient described that her mother experienced headaches and limb weakness after receiving Moderna booster..The patient was resting at home and did not seek medical attention. She died at home in the morning of 21-Apr-2022..No treatment medications were reported..The worldwide UID was reported as [redacted]..company commnet:This regulatory authority case concerns a 62 years old female patient with no relevant medical history reported, who experienced the unexpected fatal serious (seriousness criterion death) events of headache, muscular weakness, which occurred 6 days after third dose of mRNA-1273 vaccine. The patient was noted to have received one dose with ASTRAZENECA COVID-19 VACCINE (COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) 5 months 7 days prior to mRNA-1273 (Interchange of vaccine products).It is reported that after booster vaccine patient had headache and limb weakness, patient was resting at home did not seek any medical attention. Patient died on 21-Apr-2022.Reported cause of death was Headache and Weakness of limbs. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 is not affected by this report. The events were assessed as serious as per Regulatory Authority's report.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 06-May-2022 and was forwarded to Moderna on 06-May-2022. .This regulatory authority case was reported by a consumer and describes the occurrence of MALNUTRITION (Prolonged nutrient deficiency), CARDIAC ARREST (Advanced age with concomitant cardiac arrest), MOBILITY DECREASED (Inferior mobility), DECREASED APPETITE (Do not want to eat, do not drink), PERSONALITY CHANGE (Personality-changed (dropped a little of his good temper and mischievousness)), COVID-19 IMMUNISATION (Revaccination with different covid-19 vaccine), FATIGUE (Wearers and need to bed earlier, just want to sleep), GENERAL PHYSICAL HEALTH DETERIORATION (Tackled by) and MULTIPLE ORGAN DYSFUNCTION SYNDROME (Multiorgan failure) in a 94-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 016G21A) for COVID-19 vaccination. . .Co-suspect products included non-company products INFLUENZA VACCINE INACT SPLIT 4V (EFLUELDA) for an unknown indication, TOZINAMERAN (COMIRNATY) for an unknown indication and TOZINAMERAN (COMIRNATY) for an unknown indication.. .The patient's past medical history included Arm fracture, Colon cancer and Diarrhoea (as an allergic reaction after a penicillin cure after urinary tract infections.)..Concurrent medical conditions included Penicillin allergy and Angina pectoris.. .On 04-Jun-2021, the patient received first dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form..On 21-Jul-2021, the patient received second dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form..On 04-Nov-2021, the patient received dose of INFLUENZA VACCINE INACT SPLIT 4V (EFLUELDA) (unknown route) .7 milliliter..On 28-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. In 2021, the patient experienced FATIGUE (Wearers and need to bed earlier, just want to sleep) (seriousness criteria death and medically significant). In December 2021, the patient experienced MOBILITY DECREASED (Inferior mobility) (seriousness criteria death and medically significant),

Case ID	WW Identifier	Narrative Complete
		DECREASED APPETITE (Do not want to eat, do not drink) (seriousness criteria death and medically significant), PERSONALITY CHANGE (Personality-changed (dropped a little of his good temper and mischievousness)) (seriousness criteria death and medically significant) and GENERAL PHYSICAL HEALTH DETERIORATION (Tackled by) (seriousness criteria death and medically significant). On 28-Dec-2021, the patient experienced COVID-19 IMMUNISATION (Revaccination with different covid-19 vaccine) (seriousness criteria death and medically significant). On an unknown date, the patient experienced MALNUTRITION (Prolonged nutrient deficiency) (seriousness criteria death and medically significant), CARDIAC ARREST (Advanced age with concomitant cardiac arrest) (seriousness criteria death and medically significant) and MULTIPLE ORGAN DYSFUNCTION SYNDROME (Multiorgan failure) (seriousness criteria death and medically significant). The patient died on 15-Jan-2022. The reported cause of death was Unspecified nutritional deficiency, Cardiac arrest and Multi organ failure. It is unknown if an autopsy was performed. . . .The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown.. . . .No concomitant medications were provided..No treatment information was provided...COMPANY COMMNET: This regulatory authority case concerns a 94 years old female patient with relevant past medical history of colon cancer, who experienced unexpected fatal serious events of malnutrition, cardiac arrest, mobility decreased, decreased appetite, personality change, fatigue, general physical health deterioration, multiple organ dysfunction, which occurred unspecified days after third dose of mRNA-1273 vaccine. Additionally Covid-19 immunization is also reported. The patient was noted to have received two doses with COMINARTY 5 months 7 days prior to mRNA-1273 (Interchange of vaccine products). Patient died on 15-Jan-2022. Reported cause of death was Unspecified nutritional deficiency, Cardiac arrest and Multi organ failure. It is unknown if an autopsy was performed. past medical history of colon cancer remains as confounding for the events malnutrition, decreased appetite, fatigue. The benefit-risk relationship of mRNA-1273 is not affected by this report. The event was assessed as serious as per Regulatory Authority´s report.
[redacted]		This case was received via European Medicines Agency (Reference number [redacted] on 09-May-2022 and was forwarded to Moderna on 09-May-2022. .This regulatory authority case was reported by a physician and describes the occurrence of ASTHENIA (Strength loss of), DEMENTIA ALZHEIMER'S TYPE (Alzheimer's disease), ASPIRATION (Aspiration), DYSPHAGIA (Dysphagia), DYSARTHRIA (Dysarthria), ATONIC SEIZURES (Drop seizures), DYSPNOEA (Dyspnoea), QUADRIPLEGIA (Tetraplegia) and PALLIATIVE CARE (Palliative care) in an 88-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 092F21A) for COVID-19 vaccination. . .Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for Prophylactic vaccination.. .The patient's past medical history included Depressive episode..Concurrent medical conditions included Polyneuropathy in 2014, Hyperlipoproteinemia and Arterial hypertension.. .On 16-Mar-2021, the patient received first dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form..On 19-Apr-2021, received second dose of TOZINAMERAN (COMIRNATY) (unknown route) dosage was changed to 2 dosage form..On 09-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 05-Jan-2022, the patient experienced ASTHENIA (Strength loss of) (seriousness criteria death, hospitalization and life threatening), DEMENTIA ALZHEIMER'S TYPE (Alzheimer's disease) (seriousness criteria death, hospitalization and life threatening), ASPIRATION (Aspiration) (seriousness criteria death, hospitalization and life threatening), DYSPHAGIA (Dysphagia) (seriousness criteria death, hospitalization and life threatening), DYSARTHRIA (Dysarthria) (seriousness criteria death, hospitalization and life threatening), ATONIC SEIZURES (Drop seizures) (seriousness criteria death, hospitalization and life threatening) and DYSPNOEA (Dyspnoea) (seriousness criteria death, hospitalization and life threatening). On 04-Mar-2022, the patient experienced QUADRIPLEGIA (Tetraplegia) (seriousness criteria death, hospitalization and life threatening). On 21-Apr-2022, the patient experienced PALLIATIVE CARE (Palliative care) (seriousness criteria death, hospitalization and life threatening). The patient died on 27-Apr-2022. The reported cause of death was progression of alzheimer's disease. It is unknown if an autopsy was performed. . . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .No concomitant product use was provided...No treatment medication was provided...Company Comment: This regulatory case concerns an 88-year-old, female patient with pre-existing arterial hypertension, polyneuropathy and hyperlipoproteinemia, who experienced the unexpected, serious (fatal, life-threatening, hospitalized) events of Dementia Alzheimer's type, along with the AESI Atonic seizures, events Dysarthria, Dysphagia, Aspiration, Dyspnoea, Asthenia, and with Quadriplegia. Palliative care was reported as an additional event which was provided to the patient during the last week of life. The events of dementia Alzheimer's type, dysarthria, dysphagia, aspiration, dyspnoea and asthenia occurred approximately a month after receiving mRNA-1273, given as booster dose; while quadriplegia started 3 months post-vaccination. The patient also received

Case ID	WW Identifier	Narrative Complete
		Tozinameran COVID-19 vaccine as primary series approximately 8 months prior to mRNA-1273. Course during hospital stay, diagnostic procedures conducted and treatment details were not provided in the case. The patient died 4.5 months after receiving mRNA-1273, with progression of Alzheimer's disease as reported cause of death. It is unknown if autopsy was performed. The patient's hypertension and hyperlipoproteinemia could be risk factors to the occurrence of a cerebrovascular event which in turn, could be a confounder to the dysarthria, dysphagia, aspiration, dyspnoea, asthenia and quadriplegia; while polyneuropathy could be a confounder to dysphagia, dyspnoea and asthenia. Additionally, the patient's hypertension could have contributed to a faster progression of Alzheimer's. Quadriplegia, asthenia, dysphagia and dysarthria can be clinical presentations in late-stage Alzheimer's. Tozinameran vaccine was also cited as co-suspect in this case. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report.
[redacted]		This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (ENCEPHALITIS VIRAL VERSUS AUTOIMMUNE, IN ETIOLOGY) in a 39-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 068F21A) for COVID-19 vaccination. . .Co-suspect products included non-company products COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) for an unknown indication and COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) for an unknown indication.. .No Medical History information was reported.. .On 14-Jul-2021, the patient received dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) (Intramuscular) 1 dosage form..On 13-Sep-2021, the patient received dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) (Intramuscular) 1 dosage form..On 05-Jan-2022, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. Death occurred on 19-Mar-2022 The cause of death was not reported. It is unknown if an autopsy was performed. . . .For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments.. .No concomitant medications were reported. ..No treatment medication was provided...World wide UID reported as [redacted]..Company Comment: .This is a regulatory case concerning a 39-year-old female patient with no reported medical history, who had a fatal outcome with unexpected serious event of Death (reported as viral encephalitis versus autoimmune in etiology), which led to hospitalization, 73 days after receiving a dose of mRNA-1273 vaccine. Patient had received 2 doses of AstraZeneca COVID-19 vaccine approximately 4 months prior to mRNA-1273 vaccination (Interchange of vaccine products). The clinical course leading to demise and the cause of death were not reported. It is unknown whether an autopsy was performed. No further details about the diagnostic procedures and treatments were provided. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event's seriousness assessed as per Regulatory Authority reporting.
[redacted]		This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (BRONCHIAL ASTHMA IN ACUTE EXACERBATION, CEREBROVASCULAR DISEASE INFARCT WITH LEFT SIDED RESIDUALS, HYPERTENSION STAGE II, DYSLIPIDEMIA, COVID SUSPECT) in a 53-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 061G21A) for COVID-19 vaccination. . .Co-suspect products included non-company products COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) for an unknown indication and COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) for an unknown indication.. .No Medical History information was reported.. .On 17-May-2021, the patient received dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) (Intramuscular) 1 dosage form..On 26-Jul-2021, the patient received dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) (Intramuscular) 1 dosage form..On 19-Jan-2022, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. Death occurred on 25-Apr-2022 The cause of death was not reported. It is unknown if an autopsy was performed. Not Provided . . .For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments.. .Patient also experienced difficullty of breathing and No other signs and symptoms..The concomitant history was not reported. The treatment history was not provided...Company Comment: .This is a regulatory case concerning a 53-year-old female patient with no reported medical history, who had a fatal outcome with unexpected serious event of Death (reported as BRONCHIAL ASTHMA IN ACUTE EXACERBATION, CEREBROVASCULAR DISEASE INFARCT WITH LEFT SIDED RESIDUALS, HYPERTENSION STAGE II, DYSLIPIDEMIA, COVID SUSPECT), which led to hospitalization, 3 months after receiving a dose of mRNA-1273 vaccine. Patient had received 2 doses of AstraZeneca COVID-19 vaccine

Case ID	WW Identifier	Narrative Complete
		approximately 6 months prior to mRNA-1273 vaccination (Interchange of vaccine products). Patient also experienced difficulty of breathing. The detailed clinical course leading to demise and the cause of death were not reported. It is unknown whether an autopsy was performed. No further details about the diagnostic procedures and treatments were provided. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event's seriousness assessed as per Regulatory Authority reporting.
[redacted]		This case was received via Takeda Pharmaceuticals (Reference number: [redacted] on 11-May-2022 and was forwarded to Moderna on 13-May-2022. . This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a nurse, was received via the PMDA (Ref, [redacted]. On 14-Jun-2021, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 05-Jul-2021, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 27-Feb-2022, at 10:15, the patient received the 3rd vaccination with this vaccine. From immediately after the vaccination, the patient continued to have no symptoms including adverse reactions. At 22:00, the patient went to bed. On 28-Feb-2022, around 00:55, while in bed, the patient suddenly complained of chest discomfort and was raced to the emergency outpatient department of the reporting hospital. At 01:10, when the ambulance team arrived, the patient had depressed level of consciousness with about 3 of JCS. However, poor oxygenation with Sp02 of 87% was noted under administration of 10 L of oxygen, and assisted ventilation was started. At 01:25, the patient got into in a state of unrest immediately before the arrival at the reporting hospital. Immediately after visiting the hospital, the condition worsened, including decreased blood pressure, bradycardia, and dilated pupils. There was no spontaneous respiration, and the carotid artery was impalpable; thus, the patient was diagnosed with cardio-respiratory arrest. Chest compressions was started, and BVM ventilation were continued. Effective cardiopulmonary resuscitation was continued, but the family member requested discontinuation of the cardiopulmonary resuscitation. At 01:40, the patient was confirmed dead. CT was performed, but the cause of death was unknown. An autopsy was recommended to determine the cause, but it was declined, and it was concluded that the direct cause of death was acute cardiac death. The outcome of chest discomfort, depressed level of consciousness, poor oxygenation, state of unrest, decreased blood pressure, bradycardia, dilated pupils, and cardio-respiratory arrest was reported as fatal. Follow-up investigation will be made. ..Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
[redacted]		This case was initially received via European Medicines Agency (Reference number: [redacted] on 13-May-2022. The most recent information was received on 06-Jun-2022 and was forwarded to Moderna on 06-Jun-2022. .This regulatory authority case was reported by a physician and describes the occurrence of ABDOMINAL PAIN UPPER (Whether pain), CEREBROVASCULAR ACCIDENT (Embolic apoplexes) and COLON CANCER (Sigma Ca) in a 60-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. . .Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 immunisation.. .Previously administered products included for Product used for unknown indication: Comirnaty and EX3599 on 29-Apr-2021..Past adverse reactions to the above products included No adverse event with Comirnaty and EX3599.. .On 20-May-2021, the patient received second dose of TOZINAMERAN (COMIRNATY) (unknown route) .3 milliliter..On 07-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 25-Jan-2022, the patient experienced ABDOMINAL PAIN UPPER (Whether pain) (seriousness criteria death, hospitalization, disability, medically significant and life threatening), CEREBROVASCULAR ACCIDENT (Embolic apoplexes) (seriousness criteria death, hospitalization, disability, medically significant and life threatening) and COLON CANCER (Sigma Ca) (seriousness criteria death, hospitalization, disability, medically significant and life threatening). The reported cause of death was whether pain, embolic apoplexes and sigma ca. It is unknown if an autopsy was performed. . . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .No concomitant medications were provided..No treatment medications were reported...Company Comment: .This is a regulatory case concerning a 60-year-old male patient with no medical history reported, who experienced the unexpected serious fatal (life-threatening, disability, medically significant,) adverse event of special interest Cerebrovascular accident (described as embolic stroke/apoplexy), and unexpected fatal serious (life-threatening, disability, medically significant) events of Abdominal pain upper and Colon cancer (described as sigma cancer), which led to hospitalization, 49 days after receiving third dose of mRNA-1273 vaccine. Patient had received 2 doses of Comirnaty COVID-19 vaccine approximately 7 months prior to mRNA-1273 vaccination (Interchange of vaccine products). Reported cause of death is abdominal pain upper, embolic apoplexes and sigma ca. Date of death is unknown, autopsy results unknown. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness assessed as per Regulatory Authority reporting.... .Most recent FOLLOW-UP information incorporated above

Case ID	WW Identifier	Narrative Complete
		includes:.On 06-Jun-2022: Follow-up received contains: Medical history updated, Suspect vaccine details updated, Co-suspect vaccine Comirnaty added, Event verbatim updated, Seriousness criteria for all events added as Death, Outcome of all events updated from Not Recovered to Fatal.
[redacted]		This case was initially received via European Medicines Agency (Reference number: [redacted] on 16-May-2022. The most recent information was received on 01-Jun-2022 and was forwarded to Moderna on 01-Jun-2022. .This regulatory authority case was reported by a physician and describes the occurrence of CIRCULATORY COLLAPSE (Going down on toilet, diarrhoea, resuscitation setting on arrival, can start from going out on the toilet within minutes, already aystolie did not succeed, madam deceased), DIARRHOEA (Going down on toilet, diarrhoea, resuscitation setting on arrival, can start from going out on the toilet within minutes, already aystolie did not succeed, madam deceased) and RESUSCITATION (Going down on toilet, diarrhoea, resuscitation setting on arrival, can start from going out on the toilet within minutes, already aystolie did not succeed,madam deceased) in a 69-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. . .The patient's past medical history included Diverticulitis, Hypothyroidism (no medication now), Polymyalgia rheumatica (polymalgic rheumatics, March 2022, polyarthrosis without underlying Rheumatic disease) in March 2022, Type 2 diabetes mellitus (no medication now), CVA in 2021, Gastric bypass and Lichen sclerosus..Previously administered products included for Product used for unknown indication: Pfeizer COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST on 31-Mar-2021, Pfeizer COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST on 01-Jul-2021, Moderna COVID-19 VACCIN MODERNA INJVLST 0 and25MLCOVID-19 VACCIN MODERNA INJVLST on 01-Dec-2021..Past adverse reactions to the above products included No adverse event with Moderna COVID-19 VACCIN MODERNA INJVLST 0,25MLCOVID-19 VACCIN MODERNA INJVLST, Pfeizer COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST, Pfeizer COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST..Concurrent medical conditions included COPD (class 2), Polyarthritis, High cholesterol, Hypertension and Shoulder prosthesis user (shoulder prosthesis straight)..Concomitant products included CLOPIDOGREL (CLOPIDOGREL TEV), HYDROCHLOROTHIAZIDE, LISINOPRIL (LISINOPRIL/HYDROCHLOORTHIAZIDE), QUETIAPINE FUMARATE (QUETIAPINE GH), CALCIUMCARBONAAT, ATORVASTATIN CALCIUM (ATORVASTATINE EG), BECLOMETASONE DIPROPIONATE (APO-BECLOMETHASONE) and PANTOPRAZOLE SODIUM SESQUIHYDRATE (PANTOPRAZOLO) for an unknown indication.. ..On 07-Apr-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 09-Apr-2022, the patient experienced EAR HAEMORRHAGE (Blood from the right ear) and INFLUENZA LIKE ILLNESS (From 9 april flu, ie cold and headache, no coughing, ?not fit?). 09-Apr-2022, the patient experienced MALAISE (Don't feel good). On 12-Apr-2022, the patient experienced INSOMNIA (Night from 12 to 13 and from 13 to 14 not slept well). On 13-Apr-2022, the patient experienced NAUSEA (Night 13 to 14 not slept well because of heavy arms, nauseous, not good) and LIMB DISCOMFORT (Night 13 to 14 not slept well because of heavy arms, nauseous, not good). On 14-Apr-2022, the patient experienced CIRCULATORY COLLAPSE (Going down on toilet, diarrhoea, resuscitation setting on arrival, can start from going out on the toilet within minutes, already aystolie did not succeed, madam deceased) (seriousness criterion death), DIARRHOEA (Going down on toilet, diarrhoea, resuscitation setting on arrival, can start from going out on the toilet within minutes, already aystolie did not succeed, madam deceased) (seriousness criterion death), HAEMATOMA (At death also some bruises on the arms that are also edematous) and OEDEMA PERIPHERAL (At death also some bruises on the arms, which are also edematous.). 14-Apr-2022, the patient experienced RESUSCITATION (Going down on toilet, diarrhoea, resuscitation setting on arrival, can start from going out on the toilet within minutes, already aystolie did not succeed,madam deceased) (seriousness criterion death). The patient died on 14-Apr-2022. The reported cause of death was suspicion myocardial infarction (registered as primary cause of death). An autopsy was not performed. At the time of death, NAUSEA (Night 13 to 14 not slept well because of heavy arms, nauseous, not good), INSOMNIA (Night from 12 to 13 and from 13 to 14 not slept well), EAR HAEMORRHAGE (Blood from the right ear), LIMB DISCOMFORT (Night 13 to 14 not slept well because of heavy arms, nauseous, not good), MALAISE (Don't feel good) and INFLUENZA LIKE ILLNESS (From 9 april flu, ie cold and headache, no coughing, ?not fit?) had not resolved and HAEMATOMA (At death also some bruises on the arms that are also edematous) and OEDEMA PERIPHERAL (At death also some bruises on the arms, which are also edematous.) outcome was unknown. . . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .No treatment details were reported...Company Comment: This regulatory case concerns a 69-year-old female patient with relevant medical history of Hypertension, High cholesterol, Chronic

Case ID	WW Identifier	Narrative Complete
		obstructive pulmonary disease, Type 2 diabetes mellitus who experienced the serious fatal unexpected events of Circulatory collapse, Diarrhoea and Resuscitation 7 days after a dose of mRNA-1273 vaccine. It was reported patient going down on toilet, with diarrhoea, tried resuscitation within minutes, but asystole, could not succeed and patient died. The reported cause of death was Myocardial infarction (reported as suspicion myocardial infarction (registered as primary cause of death)). Patient died 7 days after mRNA-1273 vaccine. Autopsy was not performed. Patient also had experienced non-serious events of nausea, Insomnia, Haematoma, Ear haemorrhage, Limb discomfort, Oedema peripheral, Malaise and Influenza like illness few days (2 to 6 days) after mRNA-1273 vaccine. Patient has received initial schedule of vaccinations with TOZINAMERAN (interchange of vaccine products) noted. Elderly age and mentioned medical history could be confounder for the event Circulatory collapse and the fatal outcome. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting.. .Most recent FOLLOW-UP information incorporated above includes:.On 01-Jun-2022: Follow up document received contains medical history and events onset date were updated. Concomitant dugs and events were added..On 01-Jun-2022: Follow up document received contains event verbatim and concomitant drug (Pantoprazolo) were updated.
[redacted]		This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted]) on 13-May-2022. The most recent information was received on 31-May-2022 and was forwarded to Moderna on 07-Jun-2022. .This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a (physician), was received via the PMDA (Ref, [redacted]. On 31-May-2022, follow-up information was received from a physician. On 10-Jul-2021, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 31-Jul-2021, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 24-Mar-2022, the patient complained of abdominal pain and diarrhea when going to work. On 25-May-2022, the patient received the 3rd vaccination with this vaccine. On 28-May-2022, the patient was absent without notice. On 29-May-2022, the patient was absent without notice. Around 17:00, the patient complained of chills, so an ambulance call was made, but the patient refused to be transported. On 30-Mar-2022, around 10:00, myocarditis developed. Thereafter, the patient was found dead, which a sudden death. On 31-May-2022, approximately 27 hours after death, administrative autopsy was conducted. The cause of death was acute circulatory failure with dehydration. There were findings of sudden death. The heart weight was 386 g. There were multicentric focal inflammatory cell infiltration (mainly macrophage) in the interstitium around the myocardial small vein, oedema, eosinophilic myocardium, and undular degeneration, which showed findings of myocarditis (myocardial interstitial inflammation). Mild inflammatory cell infiltration (mainly macrophage) was noted around small vessels in adventitia of the middle region of the right coronary artery and left anterior descending artery, which showed findings of coronary adventitial perivasculitis. At autopsy, LMT: 25%, LAD: 25%, CX: 25%, RCA: 25%, and coronary artery stenosis was noted. Blood tests showed NT-proBNP 15,900 pg/mL. CoV-2 S-IgG antibody was positive, and the concentration was 31,200 AU/mL. CT showed no abnormal findings. The outcome of myocarditis and acute circulatory failure with dehydration was reported as fatal. The outcome of coronary adventitial perivasculitis and coronary artery stenosis was unknown. No follow-up investigation will be made. Reporter comments continuation: The occurrence of adverse events is not related to pathological factors of underlying diseases and complications. There is multicentric focal inflammatory cell infiltration mainly of macrophage in the myocardium. While usual viral myocarditis has conspicuous images of attacking the myocardium, myocarditis after the vaccination with this vaccine often shows inflammatory cell infiltration mainly in the myocardial interstitium, and this case corresponds to the above infiltration. Other factors are unknown, but this case is associated with ischaemic enterocolitis. Follow-up received on 31-MAY-2022 Updated: Patient Information, Other Relevant History, Event Information, Narrative, Reporter Comments.. Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
[redacted]		This case was initially received via United Kingdom MHRA (Reference number: [redacted]) on 17-May-2022. The most recent information was received on 09-Jun-2022 and was forwarded to Moderna on 09-Jun-2022. .This regulatory authority case was reported by a consumer and describes the occurrence of CHOKING (choking), DELIRIUM (delerium), AGITATION (Agitation), CONFUSIONAL STATE (Confusion), FALL (Fall), PSYCHOMOTOR HYPERACTIVITY (Hyperactivity), PERSONALITY CHANGE (Personality change), SEIZURE (Seizure), PRODUCTIVE COUGH (Sputum), MALAISE (Feeling sick), HYPOTENSION (Blood pressure low), CARDIAC ARREST (Cardiac arrest) and AGONAL RESPIRATION (Agonal respiration) in a 90-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. . .Co-suspect products included non-company products COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) for

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		COVID-19 vaccination, TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 vaccination and COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) for COVID-19 vaccination.. .Patient had a long history of being treated for hyperparathyroidism, anxiety, depression, arthritis (possibly ankylosing spondylitis), and blood pressure variation, as well as problems with persistent redness round her eyelids. She had a few hospital admissions for fainting (over a period of several years) and then one for the fall and broken femur- partly caused because she was agitated. .The patient's past medical history included Prolonged periods (Occasional more elevated periods - but none to the reporter knowledge for years before the first COVID vaccine.), Hyperparathyroidism, Blood pressure fluctuation, Fainting, Eyelid rash, Sarcoma (lost an arm to a sarcoma in the 1980s) and Femur fracture (broken femur)..Concurrent medical conditions included Depression (Chronic), Arthritis (Patient had arthritis (possibly ankylosing spondylitis)) and Anxiety (Chronic).. .On 22-Jan-2021, the patient received first dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) (unknown route) 1 dosage form..On 29-Jul-2021, the patient received second dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) (unknown route) 1 dosage form..On 11-Jan-2022, the patient received third dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (unknown route) 1 dosage form..On 28-Apr-2022, the patient received fourth dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 08-Mar-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced DELIRIUM (delerium) (seriousness criteria death and hospitalization). In March 2021, the patient experienced CHOKING (choking) (seriousness criteria death and hospitalization). On 14-May-2022, the patient experienced SEIZURE (Seizure) (seriousness criteria death and hospitalization), MALAISE (Feeling sick) (seriousness criteria death and hospitalization) and HYPOTENSION (Blood pressure low) (seriousness criteria death and hospitalization). On an unknown date, the patient experienced AGITATION (Agitation) (seriousness criteria death and hospitalization), CONFUSIONAL STATE (Confusion) (seriousness criteria death and hospitalization), FALL (Fall) (seriousness criteria death and hospitalization), PSYCHOMOTOR HYPERACTIVITY (Hyperactivity) (seriousness criteria death and hospitalization), PERSONALITY CHANGE (Personality change) (seriousness criteria death and hospitalization), PRODUCTIVE COUGH (Sputum) (seriousness criteria death and hospitalization), CARDIAC ARREST (Cardiac arrest) (seriousness criteria death and hospitalization) and AGONAL RESPIRATION (Agonal respiration) (seriousness criteria death and hospitalization). The patient died on 14-May-2022. The reported cause of death was Delirium, Choking and Cardiac arrest. It is unknown if an autopsy was performed. . . . . .Concomitant product use was not provided by the reporter. .It was reported that A few weeks after the first dose of the vaccine (22 January 2021), she started to have choking fits. She then had to be admitted to hospital (29 March) with a variety of symptoms including agitation, personality change, confusion and delirium..Patient's second dose had been delayed due to the concerns about the possible adverse reaction to the first dose..After partial recovery and stays in care homes and at home, she had a second dose,of AZ vaccine. A few weeks after the second dose she was again hyper-active, and fell and broke her femur and was hospitalized..Patient had a booster dose of another COVID vaccine during her time in hospital, possibly an mRNA, possibly Pfizer. She improved gradually but a few weeks after that booster she again became agitated and confused. This had partially subsided when she had her 4th COVID vaccine, possibly Moderna, a few days ago. She again became more agitated and confused. she had a choking problem with whitish sputum, and she had a fit.She died at home with paramedics in attendance. .The reported mentioned that no post mortem was performed..It was reported that reaction did not occurred as a result of a mistake made in the administration of the vaccine.. Company Comment:.This regulatory authority case concerns a 90-year-old female patient with a medical history of Depression, Anxiety and Blood pressure fluctuation, who experienced the fatal unexpected serious events of Seizure (AESI), Choking, Delirium, Agitation, Confusional State, Fall, Psychomotor Hyperactivity, Personality Change, Productive Cough, Malaise, Hypotension, Cardiac Arrest and Agonal Respiration, that led to hospitalization and death. Few weeks after receiving the first dose of COVID-19 vaccine AstraZeneca, the patient started to have choking fits and was admitted to a hospital approximately 2 months after the first dose with symptoms of agitation, personality change, confusion and delirium. The patient partially recovered and stayed in care home and the second dose of AstraZeneca vaccine was given. Few weeks after the second dose, the patient again became hyper-active, fell and broke her femur and was hospitalized. A booster dose of AstraZeneca was given while the patient was in the hospital. The patient improved gradually but again became agitated and confused. The patient became more agitated and confused after partially subsiding few days after receiving a dose of mRNA-1273 vaccine. The patient had choking and died at home with paramedics in attendance on 14-May-2022. Diagnostic tests and treatment details were not provided in the case. The reported cause of death was Delirium, Choking

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		and Cardiac arrest. It is unknown if an autopsy was performed. At the time of the last observation, the outcome of chocking, delirium had not recovered, cardiac arrest was fatal and the rest unknown. Patient's medical history of depression and anxiety could be confounders for the events Delirium, Agitation, Confusional state, Psychomotor hyperactivity, and Personality change. Blood pressure fluctuation could be contributory to the event Hypotension. Patient's advanced age could be a contributory risk factor for the event cardiac arrest. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness assessed as reported..Most recent FOLLOW-UP information incorporated above includes:.On 24-May-2022: Medical history, event and narrative updated..On 09-Jun-2022: Significant follow-up received contains cause of death,additional events, event stop date removed (Delirium), event outcome, co-suspect product,suspect product start and stop date details and case narrative were updated.
[redacted]		This case was initially received via European Medicines Agency (Reference number: [redacted] on 18-May-2022. The most recent information was received on 19-May-2022 and was forwarded to Moderna on 19-May-2022. .This regulatory authority case was reported by a physician and describes the occurrence of SYNCOPE (Relapsing syncope) in a 76-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005884 sc 08/05/22) for COVID-19 vaccination. . .The patient's past medical history included Hypertension pulmonary on 09-Dec-2021..Previously administered products included for COVID-19 immunisation: COMIRNATY on 14-Apr-2021 and COMIRNATY on 05-May-2021..Past adverse reactions to the above products included No adverse event with COMIRNATY and COMIRNATY..Concurrent medical conditions included Diabetes..Concomitant products included PANTOPRAZOLE for Acid reflux (oesophageal), TICAGRELOR and ATORVASTATIN for Atherothrombosis, INSULIN ASPART (NOVORAPID), DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE, METFORMIN HYDROCHLORIDE (XIGDUO) and INSULIN GLARGINE (TOUJEO) for Diabetes mellitus, ACETYLSALICYLIC ACID (CARDIOASPIRIN) for Hypertension.. ..On 19-Nov-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 16-Apr-2022, after starting mRNA-1273 (Spikevax), the patient experienced SYNCOPE (Relapsing syncope) (seriousness criterion death). The patient died on 16-Apr-2022. The reported cause of death was Syncope. It is unknown if an autopsy was performed. . . .For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.. .No treatment was reported..Report was suggested by spouse.Company comment:.This regulatory authority case concerns 76-years-old, male patient with past medical history of Hypertension pulmonary from 09-Dec-2021 to 16-Apr-2022, who experienced the unexpected Fatal event of Syncope (relapsing syncope) (seriousness criteria death). Patient died after 4 month 28 days after the dose of mRNA-1273 vaccine (dose number not specified). Cause of death was reported as Syncope. However, autopsy report was not provided. It was reported that patient had received 2 doses with COMIRNATY vaccine 6 months 14 days prior to current vaccination (Interchange of vaccine products). Patient's elderly age, Interchange of vaccine products and past medical history of Hypertension pulmonary from 09-Dec-2021 to 16-Apr-2022 remains a confounder. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority's reporting.. .Most recent FOLLOW-UP information incorporated above includes:.On 19-May-2022: Follow-up received is significant. Medical History was updated, Suspect drug information was updated and Concomitant medications were added..On 31-May-2022: Follow up document received contains non significant information(senders comment were updated and historical vaccine term were translated).On 06-Jun-2022: Follow-up received included no new information.
[redacted]		This regulatory authority case was reported by an other health care professional and describes the occurrence of HEADACHE (Headache), VISION BLURRED (Blurred vision), CONTUSION (Multiple bruise over trunk and face), EYE PAIN (Eye pain) and HEADACHE (headache for about 1 week) in a 29-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. . .Previously administered products included for Drug use for unknown indication: BNT and BNT..Past adverse reactions to the above products included No adverse event with BNT and BNT..Family history included Hepatocellular carcinoma (Denied any systemic disease or family history with hematologic disease (grandfather and uncle HCC)) since an unknown date...On 25-Mar-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 25-Mar-2022, the patient experienced HEADACHE (headache for about 1 week) (seriousness criterion death). On 18-Apr-2022, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced HEADACHE (Headache) (seriousness criterion death), VISION BLURRED (Blurred vision) (seriousness criterion death), CONTUSION (Multiple bruise over trunk and face) (seriousness criterion death) and EYE PAIN (Eye pain) (seriousness criterion death). The patient was treated with HYDROXYUREA at an unspecified dose and frequency; RETINOIC ACID at an unspecified dose and frequency and MANNITOL at an unspecified dose and

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		frequency. The patient died on 02-May-2022. The reported cause of death was Headache, multiple bruise over trunk and face, Blurred vision and Eye pain. It is unknown if an autopsy was performed.. .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 24-Apr-2022, Computerised tomogram head: found intracranial hemorrhage found intracranial hemorrhage..On 24-Apr-2022, Full blood count: abnormal (abnormal) abnormal..On 30-Apr-2022, Blood pressure measurement: drop (Low) drop...For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.. .No concomitant products were reported...Mild fever for 1/2 days after COVID-19 Moderna Vaccination, but subsided and denied any discomfort. Then acute onset headache for more than a week. And subsided after visiting ENT local clinic (common cold was told). On 18-Apr-2022, Ecchymosis was noted in arm and increased since then but she denied traumatic history. .On 21-Apr-2022, Bruised eye lids in both eyes with mild eye pain was complained .On 24-Apr-2022, she was admitted to hospital due to persistent headache and blurred vision. .Drowsy consciousness and dull response associated with left side limbs weakness were noticed around 17:51 at ED. Neuro and Hematologist were consulted. Acute leukemia, suspect acute promyelocytic leukemia with hyperleukostasis and disseminated intravascular coagulation (DIC) and ICH. Progressive leukocytosis was noted, under All-trans retinoic acid (ATRA) and hydroxyurea use. Blood transfusion for DIC. Mannitol was given for ICH with mass effect. Extremely high mortality rate was informed to family. .On 28-Apr-2022, progression of ICH, coma status, palliative care. .On 30-Apr-2022, pupil dilate. ..The Worldwide UID was reported as [redacted] ..Company Comment: This regulatory authority case concerns a 29-year-old female patient, with no medical history reported, who experienced unexpected serious (fatal) events of Headache, Vision blurred, Contusion and Eye pain, which occurred 24 days post vaccination with the third dose of mRNA-1273 vaccine. The patient was noted to have received two doses of COMINARTY prior to mRNA-1273 with no reported adverse events. It was reported that patient had fever for 1-2 days after vaccination, and then subsided. Then headache for more than a week, which subsided after visiting ENT clinic (common cold was told). 24 days after the third dose of mRNA-1273 vaccine, ecchymosis was noted in arm and increased. Also bruised eye lids in both eyes with mild eye pain. Approximately 1 month after vaccination with mRNA-1273, patient was admitted at the hospital due to persistent headache and blurred vision. Abnormal hemogram was noted and a brain CT scan found intracranial hemorrhage. She was drowsy and with dull response associated with left side limbs weakness. Neurology and Hematology services were consulted. Diagnosis reported as suspect acute promyelocytic leukemia with hyperleukostasis and disseminated intravascular coagulation (DIC) and intracerebral brain hemorrhage (ICH). Progressive leukocytosis was noted. She was started on All-trans retinoic acid (ATRA) and hydroxyurea. Blood transfusion was done for DIC. Mannitol was given for ICH with mass effect. The extremely high mortality rate condition was explained to the family. Subsequently there was progression of the ICH patient went into coma status then palliative care. One month 5 days post vaccination with the 3rd dose of the mRNA-1273 vaccine, pupils were noted to be dilated and blood pressure dropped. The patient expired on 2022/05/02, one month and 7 days post vaccination with the 3rd dose of the mRNA-1273 vaccine. It is unknown if an autopsy was done. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 09-May-2022: Non-significant correction was performed on 26-May-2022. The age of the patient was updated in the company comment.
[redacted]		This regulatory authority case was reported by an other health care professional and describes the occurrence of CORONARY ARTERY DISEASE (Suspicious coronary artery disease) in a 59-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 2100686_1110418) for COVID-19 vaccination. . .Previously administered products included for Product used for unknown indication: BNT vaccine (first dose in the pediatric clinic) on 05-Jan-2022..Past adverse reactions to the above products included No adverse event with BNT vaccine.. ..On 05-Apr-2022, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 11-Apr-2022, the patient experienced CORONARY ARTERY DISEASE (Suspicious coronary artery disease) (seriousness criterion death). The patient died on 11-Apr-2022. The reported cause of death was suspicious coronary artery disease. An autopsy was performed. The autopsy-determined cause of death was suspicious coronary artery disease. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 06-May-2022, Anti-platelet factor 4 antibody test: positive (Positive) Positive.. . .For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.. .On 09-Apr-2022, the patient was found lying down in a stream bed and sent to the hospital for emergent treatment and OHCA (Out-of-hospital cardiac arrest) when arrived at the hospital. After first aid, the heartbeat was restored but the patient was not awake, then admitted into ICU for observation and treatment, followed by occurrence of multiple organ failure, hypoxic encephalopathy, hepatic

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		hematoma (grade I). On 11-Apr-2022, the consultation meeting for palliative care was held by the hospital with the family members, they attended the meeting expressed understanding and agreed to palliative care. On 11-Apr-.On 26-Apr-2022, the initial report from forensic autopsy was performed (suspicious coronary artery disease)...The Worldwide UID was reported as [redacted].Company comment: This regulatory case concerns a 59-year-old male patient with history of interchange of vaccine products, who experienced the unexpected serious (death) event coronary artery disease, 6 days after receiving the second dose of mRNA-1273 vaccine. The patient was found unconscious at his place and was shifted to hospital. Attempts were made to revive, and heartbeat was restored but patient remained unconscious and was admitted to ICU. Upon further investigations, he was found to be having, multiple organ failure, hypoxic encephalopathy, hepatic hematoma (grade I). Two days later he died, and an autopsy was performed which revealed findings suspicious of coronary artery disease. Details of concurrent conditions, medications, Investigation reports and treatment were not provided. Age of the patient could be a risk factor. 3 months prior to the Moderna dose, the patient had taken one dose of BNT covid-19 vaccine (Inappropriate schedule of vaccination). The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. The case seriousness was assessed as per Regulatory Authority report.
[redacted]		This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (Died before arrival) in a 55-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. . .Patient had no history of chronic diseases. .Previously administered products included for Product used for unknown indication: BNT vaccine on 19-Oct-2021 and BNT vaccine on 03-Dec-2021..Past adverse reactions to the above products included No adverse event with BNT vaccine and BNT vaccine.. ..On 22-Apr-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. Death occurred on 26-Apr-2022 The patient died on 26-Apr-2022. The reported cause of death was Coronary heart disease, Myocardial hypertrophy and Pulmonary edema. An autopsy was performed. . . .For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.. .No concomitant medication were provided..After the booster vaccination the patient felt physical soreness and malaise, without other discomfort. On 26-Apr-2022 patient's family found he lost breath and heartbeat at home, and sent him to hospital but he died before arrive. .No treatment medication were provided..The Worldwide unique ID number was reported as [redacted]Company comment: This regulatory authority case concerns a 55-year-old male patient with no reported medical history, who experienced unexpected fatal event of Death, 4 days after receiving third dose of mRNA-1273 vaccine in COVID 19 vaccination series. After the vaccination he felt physical soreness and malaise. 4 days later patient's family found he lost breath and heartbeat at home and sent him to hospital, but he died before arrival. Autopsy was performed and cause of death were reported as coronary heart disease, myocardial hypertrophy, and pulmonary edema. Patient received 2 doses of tozinameran COVID vaccine approximately 4 and 6 months prior to the last dose (interchange of vaccine products noted). The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.
[redacted]		This case was received via Takeda Pharmaceuticals (Reference number: [redacted] on 23-May-2022 and was forwarded to Moderna on 24-May-2022. . This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, [redacted]. On an unknown date, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 27-Feb-2022, the patient received the 3rd vaccination with this vaccine. On an unknown date, the patient experienced severe vasculitis. On 01-Mar-2022, diffuse alveolar haemorrhage and respiratory failure developed. Pyrexia of 38.3 degrees Celsius was noted. On 02-Mar-2022, the patient was referred to a nearby physician with a diagnosis of severe pneumonia. Computed tomography (CT) on admission showed diffuse infiltrative shadows mainly in the upper lung fields of both lungs. On 03-Mar-2022, the respiratory status was rapidly deteriorated. Since SpO2 became 70% to 80% even with oxygen of 15 L/min, intubation was performed, and artificial respiration was started. A large amount of foamy bloody sputum was aspirated via the intubation tube. The patient was diagnosed with diffuse alveolar hemorrhage. Steroid pulse therapy was started. On 15-Mar-2022, the mechanical ventilation was removed. On 22-Mar-2022, respiratory status worsened again, and the patient was intubated again. Pneumonia in both lower lobes was shown on the image. MRSA was detected by culture. Bacterial infection was observed. Antibiotic treatment was performed. On an unknown date, the patient suffered multiple organ failure. On 11-Apr-2022, the patient died. The outcome of severe pneumonia, and vasculitis was unknown. The outcome of diffuse alveolar hemorrhage, respiratory failure, multi-organ failure, and bacterial infection was reported as fatal. Follow-up investigation will

Case ID	WW Identifier	Narrative Complete
		be made. Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
[redacted]		This spontaneous case was reported by a consumer and describes the occurrence of PARKINSON'S DISEASE (Parkinson's disease), DEMENTIA (Dementia due to Parkinson's disease) and SEIZURE (Seizures) in a 75-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 065K21A and 030H21B) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. . .Co-suspect products included non-company products CARBIDOPA, LEVODOPA (DUOPA) for Parkinson's disease and TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 vaccination.. .The patient's past medical history included Alcohol use in 2012 and Arterial stent insertion NOS..Concurrent medical conditions included Penicillin allergy, Non-smoker and Parkinson's disease..Concomitant products included LORAZEPAM for Anxiety, QUETIAPINE FUMARATE (SEROQUEL) for Anxiety and Prophylaxis, PARACETAMOL (TYLENOL) for Pain, TRAZODONE for Prophylaxis, VENLAFAXINE, MIDODRINE, MACROGOL 3350 (MIRALAX), VITAMIN D2 and LANSOPRAZOLE (PREVACID) for an unknown indication.. .On 16-Oct-2017, the patient started CARBIDOPA, LEVODOPA (DUOPA) (Percutaneous) at an unspecified dose..On 06-Feb-2021, the patient received first dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (Intramuscular) 1 dosage form..On 27-Feb-2021, received second dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (Intramuscular) dosage was changed to 1 dosage form..On 12-Dec-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form..On 03-May-2022, received fourth dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 04-May-2022, the patient experienced SEIZURE (Seizures) (seriousness criteria death and medically significant) and PYREXIA (Fever). On an unknown date, the patient experienced PARKINSON'S DISEASE (Parkinson's disease) (seriousness criteria death and medically significant), DEMENTIA (Dementia due to Parkinson's disease) (seriousness criteria death and medically significant) and INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products). The patient was treated with Hospice care for Parkinson's disease; Hospice care for Dementia; Hospice care for Seizure and Hospice care for Pyrexia. The patient died on 12-May-2022. The reported cause of death was parkinson's disease and dementia due to parkinson's disease. It is unknown if an autopsy was performed. At the time of death, PYREXIA (Fever) had not resolved and INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) outcome was unknown. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On an unknown date, Body temperature: 104.3 f 104.3 F.. . . .Company Comment: This spontaneous case concerns a 75-year-old old male patient with concurrent condition of Parkinson's Disease and relevant medical history of Arterial stent insertion who experienced the fatal unexpected, serious (medically significant) adverse event of special interest of Seizure and fatal, unexpected (medically significant) events of Parkinson's disease and Dementia which occurred after receiving a dose of mRNA-1273 vaccine taken as fourth dose of COVID-19 immunization. He previously received mRNA-1273 approximately five months prior to the current dose but with no information on adverse event. Interchange of vaccine products is noted in this case as he received Pfizer BIONTECH COVID-19 vaccine as primary series of COVID-19 immunization. Patient has been taking several central nervous system medications and was admitted to hospice care 10 months prior to the events. Two days after the last dose of mRNA-1273 administration, he developed high grade fever (104.7 degrees Fahrenheit) and seizure. The clinical course was not provided but reported that patient died at home 8 days after the onset of seizure. Death occurred 9 days after second dose of mRNA-1273 vaccine. The cause of death was reported as Parkinson's disease and Dementia due to Parkinson's disease. It is unknown if an autopsy was performed. Dementia is a common manifestation of Parkinson's disease. Concomitant use of Venflaxine and Trazodone and occurrence of high grade fever are confounders for the event Seizure. Advanced age, medical history and low body mass index are also considered confounders for the fatal outcome. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
[redacted]		This case was received via United Kingdom MHRA (Reference number: [redacted] on 24-May-2022 and was forwarded to Moderna on 24-May-2022. .This regulatory authority case was reported by a consumer and describes the occurrence of VOMITING (vomiting), ABDOMINAL PAIN (tummy pain), FATIGUE (tiredness), COVID-19 (SARS-CoV-2 infection), DEATH (Death) and THIRST (Thirst) in a 98-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. . .The patient's past medical history included Suspected COVID-19 from 11-Apr-2022 to 18-Apr-2022..Previously administered products included for COVID-19 vaccination: SARS-COV-2 VIRUS since an unknown date, SARS-COV-2 VIRUS since an unknown date and SARS-COV-2 VIRUS since an unknown date..Past adverse reactions to the above products included No adverse reaction with SARS-COV-2 VIRUS, SARS-

Case ID	WW Identifier	Narrative Complete
		COV-2 VIRUS and SARS-COV-2 VIRUS..Concomitant products included PARACETAMOL for Gut pain.. ..On 09-May-2022, the patient received fourth dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 11-May-2022, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced COVID-19 (SARS-CoV-2 infection) (seriousness criterion hospitalization) and DEATH (Death) (seriousness criteria death and hospitalization). On an unknown date, the patient experienced VOMITING (vomiting) (seriousness criterion hospitalization), ABDOMINAL PAIN (tummy pain) (seriousness criterion hospitalization), FATIGUE (tiredness) (seriousness criterion hospitalization) and THIRST (Thirst) (seriousness criterion hospitalization). The patient died on 14-May-2022. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, VOMITING (vomiting), ABDOMINAL PAIN (tummy pain), FATIGUE (tiredness) and THIRST (Thirst) outcome was unknown and COVID-19 (SARS-CoV-2 infection) had not resolved. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On an unknown date, SARS-CoV-2 test: no - negative covid-19 test (Negative) No - Negative COVID-19 test.. . . . .The patient experienced Tummy pain, vomiting fluids, tiredness and thirsty.Patient is not enrolled in clinical trial..The patient report doesn't relate to possible myocarditis or pericarditis..The treatment history was not provided...Company Comment: This regulatory authority case concerns a 98-year-old male patient, with no relevant medical history reported, who experienced unexpected, serious fatal events (death, hospitalization) AESI Covid19 (not laboratory confirmed) with vomiting, abdominal pain, fatigue and thirst, around 2 days after receiving a fourth dose of mRNA-1273. Clinical course and treatment, and circumstances surrounding death were not reported. The cause of death was also not reported. It is not known if an autopsy was performed. The patient's advanced age could be a contributory factor for the fatal outcome. The ongoing Covid-19 pandemic could be a contributory factor for Covid19. The benefit risk relationship of mRNA-1273 is not affected by this report. Event seriousness is assessed as per regulatory authority's report.. .Most recent FOLLOW-UP information incorporated above includes:.On 26-May-2022: Follow-up information received on 26-May-2022 contains no new information.
[redacted]		This case was initially received via United Kingdom MHRA (Reference number: [redacted]) on 24-May-2022. The most recent information was received on 01-Jun-2022 and was forwarded to Moderna on 01-Jun-2022. .This regulatory authority case was reported by an other health care professional and describes the occurrence of PNEUMONIA (Pneumonia) in an 82-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 000018A) for COVID-19 vaccination. . .The patient's past medical history included Living in residential institution..Previously administered products included for COVID-19 vaccination: SARS-COV-2 VIRUS, SARS-COV-2 VIRUS and SARS-COV-2 VIRUS..Past adverse reactions to the above products included No adverse reaction with SARS-COV-2 VIRUS, SARS-COV-2 VIRUS and SARS-COV-2 VIRUS..Concurrent medical conditions included Hypertension, Vascular dementia, Atrial fibrillation, Type 2 diabetes mellitus and Chronic kidney disease stage 3..Concomitant products included BENPERIDOL, BISOPROLOL, GLICLAZIDE, LINAGLIPTIN and MIRTAZAPINE for an unknown indication.. ..On 11-May-2022, the patient received fourth dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 14-May-2022, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced PNEUMONIA (Pneumonia) (seriousness criteria death, hospitalization and medically significant). The patient was hospitalized on 14-May-2022 due to PNEUMONIA. The patient died on 15-May-2022. The reported cause of death was Pneumonia. It is unknown if an autopsy was performed. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On an unknown date, SARS-CoV-2 test: negative (Negative) Covid-19 infection status was negative... . .For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.. .Patient was generally well before receiving the vaccine. On 14-May-2022, a 999 ambulance was called, the emergency department provisional diagnosis was sepsis and the patient was admitted to the hospital..The patient's medicine was obtained in a care home. .The patient thought that this reaction did not occurred as a result of a mistake made in the administration of the vaccine..The patient's death occurred following administration of the fourth dose (2nd Booster)..A post mortem of patient was not performed..No treatment information was provided by the reporter...Company Comment: This regulatory authority case concerns a 82 year male patient with history of living in residential institution, and having concurrent illness with type 2 Diabetes mellitus, CKD Stage 3, hypertension , Vascular dementia , atrial fibrillation (Past medical) , who experienced Serious (fatal , hospitalization , medically significant) , unexpected event of Pneumonia which occurred 3 days post vaccination with 4 dose of mRNA-1273 vaccine in the covid 19 vaccination series. Patient previously received 3 doses of SARS-COV-2 VIRUS vaccine (brand not provided) on an unknown date. The patient was hospitalized on 14-May-2022 due to pneumonia. The patient died on 15-May-2022. The reported cause of death was Pneumonia. A post mortem of patient was not performed. On an

Case ID	WW Identifier	Narrative Complete
		unknown date, SARS-CoV-2 test was negative. Details of treatment medications and results of other laboratories/diagnostic procedures were not reported. Patient was generally well before receiving the vaccine. The age of this patient plus living in residential institution with the above mentioned multiple medical conditions are considered confounders for the event. The benefit -risk relationship of mRNA -1273 (Moderna Covid 19 Vaccine) is not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 01-Jun-2022: Follow-up received include : Historical vaccine (SARS COV-2 Vaccine) added, Cause of death (Pneumonia) added, Suspect Moderna Vaccine (Indication, action taken) updated, iNarrative updated.
[redacted]		This case was received via Takeda Pharmaceuticals (Reference number: [redacted] on 23-May-2022 and was forwarded to Moderna on 25-May-2022. . This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, [redacted]. The vaccine recipient made regular visits to a respiratory clinic for interstitial pneumonia and pulmonary fibrosis, was being given oxygen at home, and was taking anticoagulants. On an unknown date, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 24-Mar-2022, the patient received the 3rd vaccination with this vaccine. On 29-Mar-2022, around 06:00, the patient suddenly experienced dyspnea and was raced to a medical institution. At 13:00, the patient was in a state of severe respiratory failure and was transferred urgently to the reporting hospital with NIPPV. On admission, the patient was intubated because Sp02 was 25.4. During intubation, bloody foamy sputum was discharged from the tube. The artificial respiration was started, and Sp02 was 44 torr even under 100% of oxygen. At 18:00, diffuse pulmonary alveolar haemorrhage was noted. Adverse reactions to this vaccine caused vasculitis at the pulmonary capillary level, and since the patient was taking anticoagulants, diffuse pulmonary alveolar haemorrhage was considered to develop. On 30-Mar-2022, at 16:15, the patient died. The outcome of respiratory failure and diffuse pulmonary alveolar haemorrhage was reported as fatal. The outcome of vasculitis was unknown. Follow-up investigation will be made. Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 25-May-2022 and was forwarded to Moderna on 25-May-2022. .This regulatory authority case was reported by a physician and describes the occurrence of COLON CANCER (Large intestine carcinoma) and CEREBROVASCULAR ACCIDENT (Apoplexy) in a 60-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. . .Previously administered products included for COVID-19 vaccination: Comirnaty BNT162b2 on 29-Apr-2021 and Comirnaty BNT162b2 on 20-May-2021..Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Comirnaty BNT162b2.. ..On 07-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. In March 2022, the patient experienced COLON CANCER (Large intestine carcinoma) (seriousness criteria death, hospitalization and life threatening). On 28-Apr-2022, the patient experienced CEREBROVASCULAR ACCIDENT (Apoplexy) (seriousness criteria death, hospitalization and life threatening). The patient died on 29-Apr-2022. The reported cause of death was Large intestine carcinoma. It is unknown if an autopsy was performed. . . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .No concomitant medications was reported..No treatment drug details was reported..This fatal regulatory case concerns an 60-year-old male patient with reported medical history of Comirnaty BNT162b2 on 29-Apr-2021 and on 20-May-2021 who experienced the serious unexpected events of COLON CANCER and CEREBROVASCULAR ACCIDENT (AESI). The events occurred unknown days after 3rd dose of mRNA-1273 vaccine .The patient died on 29-April-2022, 145 days after vaccination. It is Unknown if Autopsy was performed. The benefit-risk relationship of drug is not affected by this report.Terms and onset dates were captured as provided .The case was assessed as serious by the Regulatory Authority's report due to Death, Life threatening and hospitalization.
[redacted]		This case was initially received via European Medicines Agency (Reference number: [redacted] on 25-May-2022. The most recent information was received on 27-Jun-2022 and was forwarded to Moderna on 27-Jun-2022. .This regulatory authority case was reported by a consumer and describes the occurrence of SEPSIS (sepsis rare bacteria,), PULMONARY EMBOLISM (longembolie), HYPOXIA (decline oxygen 63 percent), PNEUMONIA (died within 4 weeks of pneumonia), PYREXIA (hoge koorts), ARRHYTHMIA (cardiac arrhythmias, was super healthy before) and CHILLS (rillingen) in an 80-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005789BS) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. . .Previously administered products included for Product used for unknown indication: PFIZER BIONTECH COVID-19 VACCINE on 03-May-2021 and PFIZER BIONTECH

Case ID	WW Identifier	Narrative Complete
		COVID-19 VACCINE on 06-Jul-2021..Past adverse reactions to the above products included No adverse event with PFIZER BIONTECH COVID-19 VACCINE and PFIZER BIONTECH COVID-19 VACCINE..Concurrent medical conditions included Hypertension (No family history of hypertension) and Bronchitis (No family history of bronchitis)..Concomitant products included DOPAMINE HYDROCHLORIDE (SEMINIET) for an unknown indication.. ..On 04-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 18-Dec-2021, the patient experienced SEPSIS (sepsis rare bacteria,) (seriousness criterion death), PULMONARY EMBOLISM (longembolie) (seriousness criterion death), PNEUMONIA (died within 4 weeks of pneumonia) (seriousness criterion death), ARRHYTHMIA (cardiac arrhythmias, was super healthy before) (seriousness criterion death) and FEBRILE CONVULSION (febrile seizures). On 19-Dec-2021, the patient experienced HYPOXIA (decline oxygen 63 percent) (seriousness criterion death), PYREXIA (hoge koorts) (seriousness criterion death) and CHILLS (rillingen) (seriousness criterion death). The patient died on 02-Jan-2022. The reported cause of death was no more oxygen and lungs full of scars, no more alveoli. An autopsy was not performed. At the time of death, FEBRILE CONVULSION (febrile seizures) had resolved. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 18-Dec-2021, Oxygen saturation: 63 63 %..On 18-Dec-2021, longfoto: it turned out there were a lot of scars in his lun it turned out there were a lot of scars in his lungs..On 19-Dec-2021, SARS-CoV-2 test: negative (Negative) Negative.. . . . .Concomitant medication was not provided...Treatment information was not provided...Company Comment: This regulatory case concerns an 80-year-old, male patient with current medical history of Hypertension and Bronchitis, who experienced the unexpected, fatal AESI of Pulmonary embolism and Arrhythmia, unexpected, fatal outcome of Sepsis, Hypoxia, Pneumonia, Pyrexia and Chills and unexpected, non-serious AESI of Febrile convulsion. The event Sepsis, Pulmonary embolism, Pneumonia, Arrhythmia and Febrile convulsion occurred 14 days after administration of an unknown dose of mRNA-1273. The event Hypoxia, Pyrexia and Chill occurred 15 days after administration of an unknown dose of mRNA-1273. The patient had two initial doses of Pfizer approximately 5 months prior, the interval between the two doses is 64 days. The patient expired 29 days after vaccination of mRNA-1273, the reported cause of death was hypoxia and absence of alveoli in the lungs with multiple scarring, no autopsy was performed. On December 19, 2021, SARS-CoV-2 test was done which yielded a negative result. The patient's medical history of Hypertension and Bronchitis could be confounders to the events Pneumonia, Pulmonary embolism and Hypoxia. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness retained as per Regulatory Authority's report.. .Most recent FOLLOW-UP information incorporated above includes:.On 27-Jun-2022: Significant follow up appended, Updated autopsy from Unknown to No. Laboratory data added.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 27-May-2022 and was forwarded to Moderna on 27-May-2022. .This regulatory authority case was reported by a consumer and describes the occurrence of PLEURAL EFFUSION (Respiratory difficulty, massive left pleural effusion of heteroplastic genesis. Left pleural biopsy reveals non-small cell lung cancer. Subsequent clinical worsening up to death), NON-SMALL CELL LUNG CANCER (Respiratory difficulty, massive left pleural effusion of heteroplastic genesis. Left pleural biopsy reveals non-small cell lung cancer. Subsequent clinical worsening up to death) and DYSPNOEA (Respiratory difficulty, massive left pleural effusion of heteroplastic genesis. Left pleural biopsy reveals non-small cell lung cancer. Subsequent clinical worsening up to death) in an 89-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 214024 sc 09/02/2022) for COVID-19 vaccination. . .Previously administered products included for Product used for unknown indication: Comirnaty ((lotto ET1831 sc 30/06/21)) on 20-Mar-2021 and Comirnaty ((lotto EW2246 sc 31/07/21)) on 10-Apr-2021..Past adverse reactions to the above products included No adverse event with Comirnaty and Comirnaty.. ..On 27-Nov-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 10-Dec-2021, the patient experienced PLEURAL EFFUSION (Respiratory difficulty, massive left pleural effusion of heteroplastic genesis. Left pleural biopsy reveals non-small cell lung cancer. Subsequent clinical worsening up to death) (seriousness criterion death), NON-SMALL CELL LUNG CANCER (Respiratory difficulty, massive left pleural effusion of heteroplastic genesis. Left pleural biopsy reveals non-small cell lung cancer. Subsequent clinical worsening up to death) (seriousness criterion death) and DYSPNOEA (Respiratory difficulty, massive left pleural effusion of heteroplastic genesis. Left pleural biopsy reveals non-small cell lung cancer. Subsequent clinical worsening up to death) (seriousness criterion death). The reported cause of death was Non-small cell lung cancer, Dyspnea and Unilateral pleural effusion. It is unknown if an autopsy was performed. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.In 2021, Blood test: normal (normal) was in good health with blood tests without any altered values.. . . .No concomitant medication information was provided..No treatment medications were provided..Company Comment: .This is a regulatory case concerning an

Case ID	WW Identifier	Narrative Complete
		89-year-old female patient with no medical history reported, who had a fatal outcome with unexpected serious events of Non-small cell lung cancer confirmed by left pleural biopsy, Dyspnoea, and Pleural effusion, which occurred 13 days after receiving a dose of mRNA-1273 as the third dose of COVID-19 vaccine. Patient had received 2-dose primary series of Comirnaty COVID-19 vaccine with no reported adverse event, approximately 8 months prior to mRNA-1273 vaccination (Interchange of vaccine products). It was reported that the patient had was in good health with unremarkable blood tests before vaccination. Then, patient experienced respiratory difficulty and noted to have massive left pleural effusion of heteroplastic genesis. Patient underwent left pleural biopsy which revealed non-small cell lung cancer. However, patient's clinical condition worsen and led to death. It was unknown whether an autopsy was performed. The cause of death was not reported. No further details about the treatments were provided. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness assessed as per Regulatory Authority reporting.. .Most recent FOLLOW-UP information incorporated above includes:.On 02-Jun-2022: Follow up contains non significant information..On 06-Jun-2022: Follow-up contains non-significant information.
[redacted]		This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (Death) in an 81-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. . .The patient's past medical history included Renal dialysis (long-term renal dialysis)..Previously administered products included for Product used for unknown indication: ASTRAZENECA COVID-19 VACCINE (first dose) on 16-Jun-2021 and ASTRAZENECA COVID-19 VACCINE (Second dose) on 01-Oct-2021..Past adverse reactions to the above products included No adverse event with ASTRAZENECA COVID-19 VACCINE and ASTRAZENECA COVID-19 VACCINE..Concurrent medical conditions included Hypertension.. .On 29-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form..On 22-Apr-2022, received fourth dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. Death occurred on 23-Apr-2022 The patient died on 23-Apr-2022. The reported cause of death was suspected adverse reaction. An autopsy was not performed. . . .For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.. .Patient age was reported as 81.3. .The patient did not go for medical consultations, diagnosis and treatments..No concomitant medication information was reported.No treatment medication was reported.On 11 May 2022, a family member reported a case of death due to suspected adverse reaction after COVID-19 vaccination.The patient received the first and second doses of AZ and Moderna Basic Booster in hospital. There was no discomfort after inoculation. On 22 April 2022, patient was vaccinated with the fourth dose of Moderna (Booster) after renal dialysis in Hospital. There was no discomfort after administration, and returned home and moved and took rest normally. In the morning on 23 April 23, the next day, when the family member called the patient to have breakfast, it was found that the patient was cold and had no breathing and heartbeat. The patient was not dissected..The WWID number was reported as [redacted].Company comment: This regulatory authority case concerns a 81 years old male patient with no relevant medical history reported, who experienced the unexpected fatal serious (seriousness criterion death) event of death , which occurred one day after fourth dose of mRNA-1273 vaccine. The patient was noted to have received two doses with ASTRAZENECA COVID-19 VACCINE (COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) 6 months 21 days prior to mRNA-1273 (Interchange of vaccine products).It is reported that after renal dialysis in Hospital, vaccinated with fourth dose of Moderna (Booster), there was no discomfort after administration, and returned home and moved and took rest normally. In the morning on 23 April 23, the next day, when the family member called the patient to have breakfast, it was found that the patient was cold and had no breathing and heartbeat. The reported cause of death was suspected adverse reaction. An autopsy was not performed. The patient died on April 23, 2022. Patient funeral affairs have been completed smoothly. Past medical history of Renal dialysis (long-term renal dialysis) is risk factor for the event death. .The benefit-risk relationship of mRNA-1273 is not affected by this report. The event were assessed as serious as per Regulatory Authority's report.
[redacted]		This regulatory authority case was reported by an other health care professional and describes the occurrence of HYPOAESTHESIA (Numbness of limbs) and PYREXIA (Fever) in a 63-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. . .Patient had no history of past diseases. .Previously administered products included for Product used for unknown indication: Astrazeneca (Dose 2) and Astrazeneca (Dose 1)..Past adverse reactions to the above products included No adverse effect with Astrazeneca and Astrazeneca.. ..On 25-Apr-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 05-May-2022, the patient experienced HYPOAESTHESIA (Numbness of limbs) (seriousness criteria death and hospitalization) and PYREXIA (Fever) (seriousness criteria death and hospitalization). The patient died on 14-May-2022. The reported cause of death was central failure,

Case ID	WW Identifier	Narrative Complete
		suspected brainstem hemorrhage.. An autopsy was not performed. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 09-May-2022, CSF test: gbs was diagnosed (abnormal) GBS was diagnosed..On an unknown date, Computerised tomogram: brainstem hemorrhage (abnormal) Brainstem hemorrhage..On an unknown date, Nerve conduction studies: conduction block (abnormal) lower limb conduction block was found and GBS was suspected.. . .For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.. .Company comment: This fatal regulatory authority case concerns 63-year-old male patient, with no relevant medical history, who experienced the unexpected, serious (due to death) events of HYPOAESTHESIA and PYREXIA, 10 days after the dose of mRNA-1273 vaccine; considered as the third dose of the vaccine schedule. Previously he received two doses of Astrazeneca vaccine as primary doses. The cause of death was central failure, suspected brainstem hemorrhage and it occurred 19 after vaccination. As per narrative of the source document, he experienced lower limb numbness and weakness, so he was admitted, and the lower limb numbness rapidly progressed to both hands. A cerebrospinal fluid test showed Guillain-Barre syndrome and plasma exchange was started. He developed seizures and after two days he died. Patient's daughter reported that post examination the final diagnosis was concluded as neuritis, but on an unknown date a computerized tomogram revealed brainstem hemorrhage; and a nerve conduction study showed lower limb conduction block suspected of Guillain-Barre syndrome. An autopsy was not performed. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event's seriousness assessed as per Regulatory Authority's report...WWID number for the case was [redacted]Concomitant medication was not provided..Patient developed lower limb numbness and weakness in early May. On May 5, patient went to Jian Min Lu's clinic for consultations and treatments. After admission, the lower limb numbness rapidly progressed to both hands, and CSF was drawn and GBS was diagnosed and confirmed on May 11, and plasma exchange was started. Patient then developed seizures in the evening on May 12. Patient died on May 14. On May 17, patient's daughter reported that post examination the final diagnosis was concluded as neuritis. Later patient died of brainstem hemorrhage and so the anatomy was not performed. Patient's daughter reported that they wanted a relief for harm that occurred from vaccination and applied for VICP..Treatment information was not reported.
[redacted]		This regulatory authority case was reported by an other health care professional and describes the occurrence of PNEUMONIA (Pneumonia, with unknown cause) in a 50-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 048M21A_1110509) for COVID-19 vaccination. . .Previously administered products included for Product used for unknown indication: BNT vaccine (First dose) on 18-Oct-2021 and BNT vaccine (Second dose) on 30-Nov-2021..Past adverse reactions to the above products included No adverse event with BNT vaccine and BNT vaccine.. ..On 25-Apr-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 30-Apr-2022, the patient experienced PNEUMONIA (Pneumonia, with unknown cause) (seriousness criterion death). The reported cause of death was pneumonia, with cause unknown. An autopsy was performed. . . .For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.. .Relevant concomitant medications were not reported...On 30-Apr-2022, The patient was found to have shock sitting on the toilet at home, and the patient was tried to be sent to the hospital for consultations and treatment, but there were no vital signs before arrival (OHCA). After the third dose of Moderna vaccine was administered on 25-Apr-2022 and physical discomfort, cough, fever, sore hands and feet, headache and other reactions began to occur on 26-Apr-2022. No obvious trauma was found in the corpse examination..Treatment information was not provided...The family member of the patient suspected that the vaccine caused the death, and a request was made for autopsy to find out the cause. On 10-May-2022, Preliminary study report was given after judicial anatomy (pneumonia, with cause unknown). On 11-May-2022, The district management assisted in notifying the VAERS (death)..The relevant matters related to VICP was told, and the current residential address was consulted...The Worldwide UID of this case is [redacted].Company comment: This regulatory case concerns a 50-year-old male patient with no reported medical history, who experienced the unexpected fatal event of Pneumonia which occurred 5 days after third dose of mRNA-1273 vaccine in COVID 19 vaccination series. 1 day after the vaccination patient experienced physical discomfort, cough, fever, sore hands and feet, and headache. 4 days later patient was found to have shock sitting on toilet at home. Patient was sent to hospital, but there were no vital signs before arrival. Autopsy was performed with the determined cause of death as Pneumonia with cause unknown. Patient received 2 doses of Tozinameran vaccine, about 5 and 6 months respectively prior from the last dose (interchange of vaccine products noted). The benefit-risk relationship of mrna-1273 is not affected by this report.

Case ID	WW Identifier	Narrative Complete
[redacted]	[redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of CARDIOGENIC SHOCK (Cardiogenic shock) in a 43-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. . .The family member of the patient stated that the patient had no history of chronic diseases. .The patient's past medical history included Mitral valve prolapse, Ventricular hypertrophy and Cardiac catheterization..Previously administered products included for No adverse event: COVID-19 MRNA VACCINE BNT162B2 on 25-Oct-2021 and COVID-19 MRNA VACCINE BNT162B2 on 22-Jan-2022..Past adverse reactions to the above products included Product used for unknown indication with COVID-19 MRNA VACCINE BNT162B2 and COVID-19 MRNA VACCINE BNT162B2..Concurrent medical conditions included Smoker.. ..On 23-Apr-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 12-May-2022, the patient experienced CARDIOGENIC SHOCK (Cardiogenic shock) (seriousness criteria death and life threatening). The patient died on 16-May-2022. The reported cause of death was Cardiogenic shock. An autopsy was not performed. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 16-May-2022, Blood pressure measurement: unstable Unstable.. . .For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.. .No concomitant medication information was provided..No treatment medications were provided...The Worldwide UID was reported as [redacted] .Company company: This is a regulatory case concerning a 43 year-old, male patient with a history of tobacco user, Ventricular hypertrophy and Mitral valve prolapse, who experienced the Fatal, unexpected, AESI of Cardiogenic shock, approximately 19 days after the mRNA-1273 vaccine, received as the third dose of COVID-19 vaccination schedule. It was reported the patient had foot edema and flatulence symptoms about one week after vaccination. Later, because the flatulence was not improved, the patient went to a nearby clinic and was diagnosed with gastroenteritis, but the symptoms were not relieved after taking medication (not specified). Nineteen days after vaccination, the patient went to the emergency department, complaining of dyspnea for 4-5 days (reported also as respiratory asthma that became more serious) and edema of lower limbs for 2 days; where pleural effusion was discovered. Due to acute respiratory failure, the patient was intubated and transferred into ICU, but the conditions were critical. Therefore, the patient was transferred to have Extra Corporeal Membrane Oxygenation (ECMO) and cardiac catheterization intervention carried out. The patient died 23 days after vaccination. The death certificate was reported as Cardiac shock and suspected myositis. An autopsy was not performed. The mentioned medical history remains as a confounder for the fatal outcome. Additionally, Interchange of vaccine products (vaccination with two doses of COVID-19 vaccine Tozinameran approximately 3 months prior) was noted in the case. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.. .It was reported that the elder sister of the patient said that the patient had foot edema and flatulence symptoms about one week after receiving the vaccine, but the patient felt that they were side effects after vaccination, so the patient did not go to see a doctor. Later, because the flatulence was not improved, the patient went to a nearby clinic for consultations and treatments. The patient was diagnosed by the doctor to have gastroenteritis, but the symptoms of the patient were not relieved after taking drugs, and later the patient had trouble in breathing. However, the patient felt that it was caused by flatulence and still did not go to see a doctor. Until 11:00 p.m. On 12-May-2022, The patient drove to the emergency department of hospital for emergency consultations and treatments as the respiratory asthma became more serious. Complaining of dyspnea for 4-5 days and edema of lower limbs for 2 days; when the patient came to the hospital there was plural effusion. Later, due to acute respiratory failure, the patient was intubated and admitted into ICU and was given pressor, but the conditions were poor. Transferred to the MICU of the general hospital and ECMO installed and cardiac catheterization intervention carried out. ..On 16-May-2022, The blood pressure was unstable and the condition was critical. Preliminary explanations have been made. ..On 16-May-2022 at 3 p.m., The patient died due to poor condition. ..On 17-May-2022, A notice was given by the hospital that the patient died. The certificate of death diagnosis was reported as cardiac shock and suspected myositis...At present, the family member prefers not to have dissection carried out...It was reported that the elder sister of the patient said that the patient had foot edema and flatulence symptoms about one week after receiving the vaccine, but the patient felt that they were side effects after vaccination, so the patient did not go to see a doctor. Later, because the flatulence was not improved, the patient went to a nearby clinic for consultations and treatments. The patient was diagnosed by the doctor to have gastroenteritis, but the symptoms of the patient were not relieved after taking drugs, and later the patient had trouble in breathing. However, the patient felt that it was caused by flatulence and still did not go to see a doctor. Until 11:00 p.m. On 12-May-2022, The patient drove to the emergency department of hospital for emergency consultations and treatments as the respiratory asthma became more serious. Complaining of dyspnea for 4-5 days and edema of lower limbs for 2 days; when the patient came to

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		the hospital there was plural effusion. Later, due to acute respiratory failure, the patient was intubated and admitted into ICU and was given pressor, but the conditions were poor. Transferred to the MICU of the general hospital and ECMO installed and cardiac catheterization intervention carried out. ..On 16-May-2022, The blood pressure was unstable and the condition was critical. Preliminary explanations have been made. ..On 16-May-2022 at 3 p.m., The patient died due to poor condition. ..On 17-May-2022, A notice was given by the hospital that the patient died. The certificate of death diagnosis was reported as cardiac shock and suspected myositis...At present, the family member prefers not to have dissection carried out...No concomitant medication information was provided..No treatment medications were provided...The Worldwide UID was reported as [redacted] [redacted]Company company: This is a regulatory case concerning a 43 year-old, male patient with a history of tobacco user, Ventricular hypertrophy and Mitral valve prolapse, who experienced the Fatal, unexpected, AESI of Cardiogenic shock, approximately 19 days after the mRNA-1273 vaccine, received as the third dose of COVID-19 vaccination schedule. It was reported the patient had foot edema and flatulence symptoms about one week after vaccination. Later, because the flatulence was not improved, the patient went to a nearby clinic and was diagnosed with gastroenteritis, but the symptoms were not relieved after taking medication (not specified). Nineteen days after vaccination, the patient went to the emergency department, complaining of dyspnea for 4-5 days (reported also as respiratory asthma that became more serious) and edema of lower limbs for 2 days; where pleural effusion was discovered. Due to acute respiratory failure, the patient was intubated and transferred into ICU, but the conditions were critical. Therefore, the patient was transferred to have Extra Corporeal Membrane Oxygenation (ECMO) and cardiac catheterization intervention carried out. The patient died 23 days after vaccination. The death certificate was reported as Cardiac shock and suspected myositis. An autopsy was not performed. The mentioned medical history remains as a confounder for the fatal outcome. Additionally, Interchange o
[redacted]		This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (Death) in a 59-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. . .The patient's past medical history included Cellulitis (cellulitis s/p in left arm and cellulitis s/p in left back waist) and Renal dialysis..Previously administered products included for COVID-19 vaccination: AZ vaccine (Dose 1) on 15-Jun-2021..Past adverse reactions to the above products included No adverse event with AZ vaccine..Concurrent medical conditions included Diabetes mellitus.. ..On 18-May-2022, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. Death occurred on 20-May-2022 The patient died on 20-May-2022. The cause of death was not reported. It is unknown if an autopsy was performed. Not Provided . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On an unknown date, Computerised tomogram: 12 12..On an unknown date, Polymerase chain reaction: positive (Positive) Positive.. . .For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.. .Patient could not be woken up at 7:00 in the morning, so First Aid Service Organization 119 was called, The patient was given On 7.0Fr Endo fix 21cm and right hand 45mm bone needle with N/S 500ml iv, Bosmin 5 Amp ivp and CPCR and then was sent to the ER. O: Current GCS: E1V1M1; Double eye pupil: 3.0 (-); No spontaneous breathing, and no pulse; 45mm bone needle on the right hand: Yes; with 7.0Fr Endo fix 21cm, the patient was sent to the ER. Left hand AV Shunt: Yes. The patient was receiving consultations and treatments, the patient was given on EKG monitor. Patients with diabetes and renal dialysis. The patient died before arriving at the hospital, and the first aid was ineffective. The PCR test was positive, and the CT value was 12. The WWID reported as: [redacted].Company Comment: This regulatory case concerns a 59-year-old female patient with diabetes mellitus on renal dialysis, who experienced the unexpected serious event of Death, 2 days after receiving mRNA-1273 vaccine given as second dose in the COVID-19 vaccination series. Cause of death was unknown. No autopsy report provided. Patient was found unable to wake up for which an emergency medical team started cardiopulmonary resuscitation along with epinephrine administration. An evaluation of Out-of-hospital cardiac arrest was made. Patient was conducted to the ER where no spontaneous breathing and pulses, and Glasgow coma scale of no eye opening, no verbal response, and no motor response were noted. PCR test was positive. Patient previously received non-company brand COVID-19 vaccine from AstraZeneca approximately 11 months prior to current mRNA-1273 vaccine. Concurrent diabetes mellitus and complications of renal dialysis along with a possible COVID-19 infection based on positive PCR positive could be considered as confounders. The benefit-risk relationship of mRNA-1273 is not affected by this report. Case seriousness was assessed as per Regulatory Authority report.
[redacted]		This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (Death) in an 80-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 2100696_1110525) for COVID-19 vaccination. . .The patient's past

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		medical history included Renal dialysis (history of chronic renal dialysis)..Previously administered products included for Product used for unknown indication: AZ vaccine on 17-Jun-2021 and AZ vaccine on 23-Sep-2021..Past adverse reactions to the above products included No adverse event with AZ vaccine and AZ vaccine.. .On 20-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form..On 05-May-2022, received fourth dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. Death occurred on 05-May-2022 The patient died on 05-May-2022. The cause of death was not reported. An autopsy was performed. . . .For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.. .No concomitant medication information was provided..On 05-May-2022, the patient received the fourth dose of vaccine when she went to undergo renal dialysis. After returning home, she had physical discomfort and weak legs and vomited water, but she was still conscious. After she lied in bed for rest, the family member found that she had no vital signs. No visible cause of trauma leading to death was found in autopsy and there was a renal dialysis tube on the right shoulder. The family member suspected that it was associated with the vaccination. In order to clarify the cause of death and mode of death, it was requested for anatomical anatomy and examination. On May 13, preliminary investigation report in judicial anatomy was showed intracranial hemorrhage, head injury and possible fall)..The worldwide UID was reported as [redacted] No treatment was provided...Company Comment: This regulatory case concerns an 80-year-old female patient on Renal dialysis, who experienced the unexpected serious event of Death on the same day after receiving mRNA-1273 vaccine given as fourth dose in the COVID-19 vaccination series. Patient was administered with the vaccine when she had her dialysis. Upon returning home, she presented with physical discomfort, weak legs, and vomiting. She then went for bed rest and was later found without vital signs. Autopsy report showed no visible cause of trauma leading to death. Judicial anatomy evaluation revealed preliminary findings of intracranial hemorrhage, head injury and a possible fall. Patient previously received 2 doses of non-company brand COVID-19 vaccine from AstraZeneca and an mRNA-1273 vaccine given as third dose in the series prior to current mRNA-1273 vaccine. Concurrent Renal dialysis possibly in the presence of complications could be considered as a confounder. The benefit-risk relationship of mRNA-1273 is not affected by this report. Case seriousness was assessed as per Regulatory Authority report.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 26-May-2022 and was forwarded to Moderna on 26-May-2022. .This regulatory authority case was reported by a pharmacist and describes the occurrence of COVID-19 PNEUMONIA (COVID-19 pneumonia) and VACCINATION FAILURE (Vaccine failure) in a 77-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3001532 and 3002339) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. . .Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 vaccination.. .The patient's past medical history included Hypertensive retinopathy, Paroxysmal atrial fibrillation (ANTICOAGULATED), Type 2 diabetes mellitus, Chronic kidney disease stage 4, Hypertension arterial, Stroke and Dyslipidaemia.. .On 09-Apr-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form..On 20-May-2021, received dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form..On 28-Jan-2022, the patient received third dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On 13-Feb-2022, the patient experienced COVID-19 PNEUMONIA (COVID-19 pneumonia) (seriousness criteria death, hospitalization and medically significant), VACCINATION FAILURE (Vaccine failure) (seriousness criteria death, hospitalization and medically significant) and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine). The patient died on 16-Feb-2022. The reported cause of death was COVID-19 pneumonia and vaccine failure. It is unknown if an autopsy was performed. At the time of death, COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) outcome was unknown. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 31-Jan-2022, SARS-CoV-2 test positive: positive (Positive) Positive..On 08-Feb-2022, SARS-CoV-2 test positive: positive (Positive) Positive..On 13-Feb-2022, Chest X-ray: cardiomegaly, pinched scf, interstitial infiltrate cardiomegaly, pinched SCF, interstitial infiltrate with increased vascular pattern, congestive hilia...On 14-Feb-2022, Chest X-ray: infiltrates and signs of pulmonary congestion infiltrates and signs of pulmonary congestion.. . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .No concomitant medication information was reported...No treatment medication was reported...Company Comment: This is a Regulatory Authority case concerning a 77-year-old male patient, with relevant medical history of paroxysmal atrial fibrillation, type 2 diabetes mellitus, chronic kidney disease stage 4, hypertension arterial, stroke and dyslipidaemia, who experienced the unexpected, serious (due to medically significant and hospitalization) fatal events of COVID-19 pneumonia (AESI) and

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		Vaccination failure, fatal events and patient´s death occurred approximately 8 months and 3 weeks after a dose (probably second dose) of mRNA-1273 vaccine. Probable first and second dose of mRNA-1273 vaccine were administered with an interval of 40 days (Inappropriate schedule of vaccine administered). Revaccination with different COVID-19 vaccine is also reported, as third dose of COVID-19 vaccination schedule was administered with Pfizer vaccine, 8 months after a dose of mRNA-1273, and 16 days before the events. Comirnaty remains as a co-suspect product. The reported cause of death was COVID-19 pneumonia and vaccine failure. It is unknown if an autopsy was performed. Patient´s medical history could be a confounder for fatal outcome. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
[redacted]		This spontaneous case was reported by a consumer and describes the occurrence of HAEMORRHAGE (Hemorrhaging), MYOCARDIAL INFARCTION (Multiple heart attacks) and THROMBOSIS (Heavy clotting) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for Prophylactic vaccination. The occurrence of additional non-serious events is detailed below. . .Co-suspect product included non-company product COVID-19 VACCINE NRVV AD26 (JNJ 78436735) (JANSSEN COVID-19 VACCINE) for Prophylactic vaccination.. .No Medical History information was reported.. .On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form and first dose of COVID-19 VACCINE NRVV AD26 (JNJ 78436735) (JANSSEN COVID-19 VACCINE) (unknown route) 1 dosage form. On an unknown date, the patient experienced HAEMORRHAGE (Hemorrhaging) (seriousness criteria death and medically significant), MYOCARDIAL INFARCTION (Multiple heart attacks) (seriousness criteria death and medically significant), THROMBOSIS (Heavy clotting) (seriousness criteria death and medically significant) and INTERCHANGE OF VACCINE PRODUCTS (patient received JANSSEN COVID-19 VACCINE). The patient died on an unknown date. The reported cause of death was Hemorrhage, Heart attack and Clot blood. It is unknown if an autopsy was performed. At the time of death, INTERCHANGE OF VACCINE PRODUCTS (patient received JANSSEN COVID-19 VACCINE) outcome was unknown. . . . .No concomitant product was provided..No treatment information were reported..Causality for JANSSEN as per reporter and mfr. was possible...Company comment. This fatal spontaneous case concerns a female patient (unknown age) with no medical history reported, who experienced the unexpected, serious (medically significant and fatal) AESI of myocardial infarction and thrombosis, and the unexpected serious event of haemorrhage. Temporal association cannot be assessed due to lack of information on onset date of the events and vaccination date. The patient received mRNA-1273 vaccine reported as booster vaccination in her COVID – 19 vaccination schedule, previously she received a dose of Janssen COVID – 19 vaccines (interchange of vaccine products could be considered). The report stated that the patient died of hemorrhaging with heavy clotting and multiple heart attacks. It was unspecified if an autopsy was performed. No further details were provided for medical review. Co – suspect product Janssen COVID – 19 vaccine remains as confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
[redacted]		This case was initially received via European Medicines Agency (Reference number: [redacted] on 03-Jun-2022. The most recent information was received on 13-Jun-2022 and was forwarded to Moderna on 13-Jun-2022. .This regulatory authority case was reported by a physician and describes the occurrence of DEATH (Found dead), MICROANGIOPATHY (Microangiopathy) and CARDIOMYOPATHY (Cardiomyopathy) in a 31-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. . .Previously administered products included for COVID-19 vaccination: JANSSEN COVID-19 VACCINE in August 2021..Past adverse reactions to the above products included No adverse event with JANSSEN COVID-19 VACCINE.. ..On 03-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 05-Jan-2022, the patient experienced DEATH (Found dead) (seriousness criterion death), MICROANGIOPATHY (Microangiopathy) (seriousness criterion death) and CARDIOMYOPATHY (Cardiomyopathy) (seriousness criterion death). The patient died on 05-Jan-2022. The reported cause of death was Acute heart failure. An autopsy was performed. The autopsy-determined cause of death was Acute heart failure. . . .The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown.. .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .No concomitant medication information was provided..No treatment medication were provided..Result of Assessment -Inconsistent causal association to immunization ..Company comment.This Regulatory case reported by a consumer, concerns a 31-year-old female patient with no relevant medical history reported, who experienced the unexpected, serious (Fatal) events of Death (found dead), and the AESI events of microangiopathy and cardiomyopathy, 01 day after receiving a dose of mRNA-1273 vaccine in the covid 19 vaccination series. The patient died on 05-Jan-2022. An autopsy was performed. The autopsy-determined cause of death was Acute heart failure. It was reported that the patient received a previous dose with Janssen covid-19 vaccine 4 months ago in

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		August 2021, with no adverse events reported for Janssen vaccine. Interchange of vaccine products was noted. Details of comorbidities, risk factors, events preceding death, concomitant medications and treatment details were not provided. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. Event seriousness assessed per Regulatory Authority report.. .Most recent FOLLOW-UP information incorporated above includes:.On 13-Jun-2022: Significant Follow up recived - Relatedness of drug to reaction/event Updated
[redacted]		This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 02-Jun-2022 and was forwarded to Moderna on 03-Jun-2022. .This regulatory authority case was reported by an other health care professional and describes the occurrence of DYSPNOEA (Dyspnea), ASTHENIA (General weakness) and COVID-19 (Positive rt pcr test) in an 81-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. . .Co-suspect products included non-company products COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (ASTRAZENECA COVID-19 VACCINE) for an unknown indication and COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (ASTRAZENECA COVID-19 VACCINE) for an unknown indication.. .No medical history information was reported. . .On 13-May-2021, the patient received dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (ASTRAZENECA COVID-19 VACCINE) (unknown route) 1 dosage form..On 08-Aug-2021, the patient received dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (ASTRAZENECA COVID-19 VACCINE) (unknown route) 1 dosage form..In January 2022, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On 29-Mar-2022, the patient experienced COVID-19 (Positive rt pcr test) (seriousness criterion death). On an unknown date, the patient experienced DYSPNOEA (Dyspnea) (seriousness criterion death) and ASTHENIA (General weakness) (seriousness criterion death). The reported cause of death was positive rt pcr test, Dyspnea and general weakness. It is unknown if an autopsy was performed. Not Provided . . .The action taken with mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown) was unknown.. .For mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown), the reporter did not provide any causality assessments.. .No concomitant medication was provided...No treatment medication was provided...Worldwide UID was reported as [redacted] This fatal regulatory case concerns an 81-year-old female patient with medical history.Of ASTRAZENECA COVID-19 VACCINE on 13-May and 8-August, 2021 who experienced the serious unexpected events of COVID-19 (AESI), DYSPNOEA and ASTHENIA.. The events occurred unknown days after a dose of mRNA-1273 vaccine .The reported cause of death was positive pcr positive test, Dyspnea and general weakness. It is unknown if an autopsy was performed. The benefit-risk relationship of drug is not affected by this report.Terms and onset dates were captured as provided .The case was assessed as serious by the Regulatory Authority´s report due to Death
[redacted]		This regulatory authority case was reported by an other health care professional and describes the occurrence of ACUTE RESPIRATORY DISTRESS SYNDROME (Acute Respiratory Distress Syndrome Secondary to Pneumonia, Severe Acute Renal Failure / Acute Kidney Injury Non Hodgkin's Lymphoma Stage IV, Diabetes Mellitus Type 2, Hypertension.), ASTHENIA (Weakness, Blurring of vision, and Anorexia), VISION BLURRED (Weakness, Blurring of vision, and Anorexia) and DECREASED APPETITE (Weakness, Blurring of vision, and Anorexia) in a 59-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 939900) for COVID-19 vaccination. . .Co-suspect product included non-company product COVID-19 VACCINE NRVV AD26 (JNJ 78436735) (JANSSEN COVID-19 VACCINE) for an unknown indication.. .No Medical History information was reported.. .On 28-Jul-2021, the patient received dose of COVID-19 VACCINE NRVV AD26 (JNJ 78436735) (JANSSEN COVID-19 VACCINE) (Intramuscular) 1 dosage form..On 07-Dec-2021, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 04-May-2022 at 8:32 AM, the patient experienced ACUTE RESPIRATORY DISTRESS SYNDROME (Acute Respiratory Distress Syndrome Secondary to Pneumonia, Severe Acute Renal Failure / Acute Kidney Injury Non Hodgkin's Lymphoma Stage IV, Diabetes Mellitus Type 2, Hypertension.) (seriousness criteria death and hospitalization), ASTHENIA (Weakness, Blurring of vision, and Anorexia) (seriousness criteria death and hospitalization), VISION BLURRED (Weakness, Blurring of vision, and Anorexia) (seriousness criteria death and hospitalization) and DECREASED APPETITE (Weakness, Blurring of vision, and Anorexia) (seriousness criteria death and hospitalization). The reported cause of death was Acute respiratory distress syndrome, Weakness, Blurring of vision and Anorexia. It is unknown if an autopsy was performed. . . .The action taken with mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) was unknown.. .For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments.. .Patient had Weakness, Blurring of vision, and Anorexia, No other signs and symptoms..The concomitant and treatment medication was not reported..Causality of events with co-suspect product was not reported...The WWUID for the case

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		was reported as [redacted].Company comment- This regulatory authority case concerns a 59-year-old male patient with no reported medical history, who experienced unexpected, serious (hospitalization, fatal) adverse event of special interest acute respiratory distress syndrome (reported as Acute Respiratory Distress Syndrome Secondary to Pneumonia, Severe Acute Renal Failure / Acute Kidney Injury Non Hodgkin's Lymphoma Stage IV, Diabetes Mellitus Type 2, Hypertension.) and unexpected, serious (hospitalization, fatal) Asthenia, Vision blurred and Decreased appetite 4 months and 27 days after vaccination with a dose of mRNA-1273. No further information was provided, and it is unknown whether an autopsy was performed. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 07-Jun-2022 and was forwarded to Moderna on 07-Jun-2022. .This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDIAL INFARCTION (Infarct myocardial) in a 66-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 0001401) for COVID-19 vaccination. . .Previously administered products included for COVID-19 vaccination: Comirnaty BNT162b2 on 14-Jun-2021 and Comirnaty BNT162b2 on 27-Jul-2021..Past adverse reactions to the above products included No adverse reaction with Comirnaty BNT162b2 and Comirnaty BNT162b2.. ..On 23-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 24-Jan-2022, the patient experienced MYOCARDIAL INFARCTION (Infarct myocardial) (seriousness criteria death and life threatening). The patient died on 24-Jan-2022. The reported cause of death was Infarct myocardial. An autopsy was performed, but no results were provided. . . .For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.. .Concomitant medication was not reported.. .No treatment information was provided...Company Comment: This is a regulatory authority case of interchange of vaccine products for this 66-year-old, female patient with past drug history of administration of two doses of Comirnaty (Pfizer/BioNTech COVID-19 mRNA vaccine), who experienced the unexpected, serious (fatal and life-threatening) AESI of myocardial infarction. The event occurred 1 day after receiving the booster dose of the mRNA-1273 vaccine. No details were provided regarding the event. Treatment information was also not provided. The patient expired on 24Jan2022 (1 day after vaccination). An autopsy was performed, however, the result was not provided. The reported cause of death was Myocardial infarction. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 07-Jun-2022: Significant live follow up - Autopsy details updated.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 07-Jun-2022 and was forwarded to Moderna on 07-Jun-2022. .This regulatory authority case was reported by an other health care professional and describes the occurrence of VACCINATION FAILURE (Vaccination failure) and COVID-19 PNEUMONIA (COVID-19 pneumonitis) in a 96-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 214005) for COVID-19 vaccination. . .Co-suspect product included non-company product COVID-19 VACCINE NRVV AD26 (JNJ 78436735) (COVID-19 VACCINE JANSSEN) for COVID-19 vaccination.. .The patient's past medical history included AFib, Gastric ulcer, Dyslipidemia, Stroke in June 2015, Arterial hypertension, Senile macular degeneration, Cardiac failure, Fracture femur in 2018, Bilateral cataracts and Haemorrhage of digestive tract..Concomitant products included AMIODARONE HYDROCHLORIDE (CORDARONE) for AFib, LINEZOLID (LOXENIL) for Arterial hypertension, CLOPIDOGREL BISULFATE (PLAVIX) for Cardiovascular event prophylaxis, METOPIMAZINE (VOGALENE) for Emesis, PANTOPRAZOLE for Gastric ulcer, IOPODATE CALCIUM (CALCIUM IPODATE) for Mineral supplementation, MIRTAZAPINE (NORSET) for Mood disorder, PARACETAMOL (DOLIPRANE) for Pain, POVIDONE (FLUIDABAK), TIMOLOL MALEATE (TIMOLOLO) and BRINZOLAMIDE for Senile macular degeneration, COLECALCIFEROL and COLECALCIFEROL for Vitamin D supplementation, HYDROXYZINE HYDROCHLORIDE, PREDNISOLONE (ATARAXOID) and DICLOFENAC SODIUM (VOLTARENE LP) for an unknown indication.. .On 20-Jul-2021, the patient received dose of COVID-19 VACCINE NRVV AD26 (JNJ 78436735) (COVID-19 VACCINE JANSSEN) (Intramuscular) 1 dosage form..On 17-Sep-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced VACCINATION FAILURE (Vaccination failure) (seriousness criteria death and hospitalization) and COVID-19 PNEUMONIA (COVID-19 pneumonitis) (seriousness criteria death and hospitalization). The patient died on 08-May-2022. The reported cause of death was Hemorrhagic shock. An autopsy was not performed. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 14-Mar-2022, SARS-CoV-2 test: positive (Positive) Positive..On 15-Mar-2022, Computerised tomogram: abnormal (abnormal) bibasal endobronchial filling with a focus of pneumonitis

Case ID	WW Identifier	Narrative Complete
		downstream at the bases, and multiple stable vertebral fractures..On 16-Mar-2022, SARS-CoV-2 test: positive (Positive) Positive..On 17-Mar-2022, SARS-CoV-2 antibody test: 84.2 (Positive) 84.2.. . .For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.. .No treatment medication reported. ..Patient had COVID pneumonitis due to the omicron variant despite a complete vaccination schedule with JANSSEN (D1) and SPIKEVAX (D2) vaccines less than 6 months before. Concomitant therapies included oxygen therapy, antibiotic therapy and corticotherapy...Company Comment: This is a regulatory case concerning a 96-year-old, female patient with reported medical history of Atrial fibrillation, Gastric ulcer, Dyslipidemia, Stroke, Arterial hypertension, Cardiac failure and Haemorrhage of digestive tract, who had a fatal outcome with unexpected serious (hospitalization) adverse event of special interest of COVID-19 pneumonia. The patient tested positive for SARS-CoV-2 and Computerized tomogram showed bibasal endobronchial filling with a focus of pneumonitis downstream at the bases approximately 6 months after receiving a dose of mRNA-1273 vaccine. The patient was treated with oxygen therapy, antibiotic therapy and corticotheraphy. The patient died approximately 8 months after receiving the said mRNA-1273 (2 months after the positive test) with Hemorrhagic shock as the cause of death. The clinical course leading to demise was not reported. Medical history of Atrial fibrillation, Gastric ulcer, Dyslipidemia, Stroke, Arterial hypertension, Cardiac failure and Haemorrhage of digestive tract remain as risk factor for the COVID-19 pneumonia. Medical history of Gastric ulcer and Haemorrhage of digestive tract remain as risk factors for the cause of Death (Hemorrhagic shock). Vaccination failure was also reported as an additional event. It should be noted the patient received other COVID-19 vaccine (Janssen) as first dose (Interchange of vaccine products) approximately 59 days prior to mRNA-1273. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event retained as serious as per Regulatory Authority.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 09-Jun-2022 and was forwarded to Moderna on 09-Jun-2022. .This regulatory authority case was reported by a physician and describes the occurrence of BONE CANCER (Malignant neoplasm of maxilla) in an 88-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 092F21A) for COVID-19 vaccination. . .Previously administered products included for COVID-19 vaccination: Comirnaty BNT162b2 on 20-Apr-2021 and Comirnaty BNT162b2 on 08-Jun-2021..Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Comirnaty BNT162b2.. ..On 08-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 14-Jan-2022, the patient experienced BONE CANCER (Malignant neoplasm of maxilla) (seriousness criteria death, hospitalization and life threatening). The patient died on 05-Mar-2022. The reported cause of death was Neoplasm of maxilla. It is unknown if an autopsy was performed. . . .For mRNA-1273 (Spikevax) (Unknown), the reporter considered BONE CANCER (Malignant neoplasm of maxilla) to be not related. . .No concomitant medication was reported. .No treatment information was reported...CC: This regulatory authority case concerns an 88 year old female patient, with no medical history reported, who experienced the Serious (fatal, life-threatening, hospitalization), unexpected event of Malignant neoplasm of maxilla, which occurred 1 month, 6 days after a dose of mRNA-1273 vaccine administration, given as the third dose. The patient died 1 month, 19 days after the mRNA-1273 vaccine administration. The reported cause of death was Neoplasm of maxilla. It is unknown if an autopsy was performed. Patient was previously vaccinated with 2 doses of Comirnaty as primary series (Interchange of vaccine products). The details of the hospitalization and treatment information were not reported. The benefit -risk relationship of mRNA -1273 is not affected by this report. Events' seriousness assessed as per RA report.
[redacted]		This regulatory authority case was reported by an other health care professional and describes the occurrence of DIZZINESS (Dizziness discomfort, and death), DISCOMFORT (Dizziness discomfort, and death) and DEATH (Dizziness discomfort, and death) in a 50-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 048M21A_1110519) for COVID-19 prophylaxis. . .Previously administered products included for Drug use for unknown indication: AZ on 21-May-2021 and AZ on 17-Aug-2021..Past adverse reactions to the above products included No adverse event with AZ and AZ.. ..On 27-Apr-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 12-May-2022, the patient experienced DIZZINESS (Dizziness discomfort, and death) (seriousness criterion death), DISCOMFORT (Dizziness discomfort, and death) (seriousness criterion death) and DEATH (Dizziness discomfort, and death) (seriousness criterion death). The patient died on 12-May-2022. The reported cause of death was Discomfort and Dizziness. An autopsy was performed. The autopsy-determined cause of death was left basal ganglia hemorrhage, Intraventricular hemorrhage and vomitus inhalation in the trachea, bronchus and larynx. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 27-May-2022, Anti-platelet factor 4 antibody test: positive (Positive) Result on 03 Jun 2022 found to be positive... . .For mRNA-1273 (Moderna

Case ID	WW Identifier	Narrative Complete
		COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.. .No relevant concomitant medications were reported. .After vaccination patient told the family member that the patient had been suffering from dizziness and discomfort. On 12-May-2022, the patient was found by the family member to be lying on the bed, and the patient was planned to be sent for medical consultations and treatments but died before arriving at the hospital. No obvious trauma w as found in corpse examination. As the family member doubted that the cause of death was related to the vaccine, an application was made to carry out autopsy to find out the cause of death. On 27-Ma-2022, preliminary study report w as given after judicial anatomy and vomitus inhalation in the trachea, bronchus and larynx were found. No treatment medication was provided...The WWID was reported as [redacted]..Company Comment: This regulatory case concerns a 50-year-old, male patient with no reported medical conditions and no concomitant medications, who experienced the unexpected, fatal events of Dizziness and Discomfort. An additional event of Death was reported pertaining to outcome of the case. The patient also experienced interchange of vaccine products wherein he received COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) as primary COVID-19 vaccine series approximately 8 months prior to mRNA-1273. The fatal events started after receiving mRNA-1273 as third COVID-19 vaccine dose. Fifteen days post-vaccination, he was seen by a family member bed-bound and was sent to a nearby hospital, but died in transit. No obvious trauma was noted during examination of the body. Autopsy was performed with preliminary report of 1. Left basal ganglia hemorrhage, intraventricular hemorrhage; 2. Vomitus inhalation in the trachea, bronchus and larynx. A post-mortem anti-platelet factor 4 antibody test was conducted which revealed a positive result, but no information provided if other diagnostic tests were conducted. Information on intake of other medications, recent infection or surgery following events was not provided in the case. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report.
[redacted]		This regulatory authority case was reported by an other health care professional and describes the occurrence of MALAISE (Body malaise) in a 45-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch nos. 939900 and 056D21A) for COVID-19 prophylaxis. . .Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for an unknown indication.. .No Medical History information was reported.. .On 19-Aug-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) dosage was changed to 1 dosage form..On 16-Sep-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) dosage was changed to 1 dosage form..On 20-Jan-2022, the patient received third dose of TOZINAMERAN (COMIRNATY) (Intramuscular) 1 dosage form..On an unknown date, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) at an unspecified dose. On 25-May-2022, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MALAISE (Body malaise) (seriousness criterion death). The patient died on 31-May-2022. The reported cause of death was body malaise. It is unknown if an autopsy was performed. . . .For mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown), the reporter did not provide any causality assessments.. .The WWID was reported as [redacted]..Concomitant product use was not provided by the reporter...Treatment information was not provided...Company comment: This is a regulatory case concerning a 45 year-old, female patient with no medical history reported, who experienced the fatal unexpected serious event of malaise, which occurred 8 months after second dose of mRNA-1273 vaccine. The patient was noted to have received one dose with Comirnaty 4 months after the mRNA-1273 (Interchange of vaccine products). Reported cause of death was malaise, date of death is 31-May-2022, autopsy results were unknown. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event seriousness is assessed as per regulatory authority's report
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 14-Jun-2022 and was forwarded to Moderna on 14-Jun-2022. .This regulatory authority case was reported by a physician and describes the occurrence of ACUTE PULMONARY OEDEMA (ACUTE PULMONARY EDEMA) in a 75-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 057G21A) for COVID-19 vaccination. . .The patient's past medical history included Stroke, Carotid artery atheroma and Arterial hypertension..Concomitant products included TOZINAMERAN (COMIRNATY) from 05-May-2021 to 05-May-2021 for COVID-19 vaccination.. ..On 17-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 23-Dec-2021, after starting mRNA-1273 (Spikevax), the patient experienced ACUTE PULMONARY OEDEMA (ACUTE PULMONARY EDEMA) (seriousness criterion death). The patient died on 26-Jan-2022. The reported cause of death was Acute pulmonary edema. It is unknown if an autopsy was performed. . . .For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.. .Company comment: This is a regulatory case concerning a 75-year-old male patient with medical history of carotid artery atheroma, arterial hypertension and

Case ID	WW Identifier	Narrative Complete
		stroke, who experienced the fatal event acute pulmonary edema, 6 days days after the third dose of COVID-19 vaccination with mRNA-1273 (previous primary vaccination with Tozineram - Comirnaty). The patient died 3 days after the event start date. Clinical course, diagnostic tests and treatment details were not provided. The reported cause of death was Acute pulmonary edema. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 is not affected by this report....The dosage text of suspect product reported as R1..Treatment information was not provided.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 16-Jun-2022 and was forwarded to Moderna on 16-Jun-2022. .This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (Few weeks after booster vaccination died suddenly unexpectedly!) in a 67-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004951) for COVID-19 vaccination. . .The person was not concerned to have known allergies. Information on risk factors or pre-existing conditions include shields hypofunction. .Previously administered products included for Prophylactic vaccination: Comirnaty BNT162b2 on 29-Apr-2021 and Comirnaty BNT162b2 on 19-May-2021..Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Comirnaty BNT162b2..Concurrent medical conditions included Hypothyreosis.. ..On 02-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 3 dosage form. Death occurred on an unknown date The cause of death was not reported. It is unknown if an autopsy was performed. . . . . .No concomitant information was reported..It was reported that patient died suddenly a few weeks after the 3rd vaccination..No treatment information was provided...CC: This regulatory case concerns a 67-year-old, male patient with a relevant medical history of hypothyroidism, who had a fatal outcome with unexpected serious event of death. The event occurred unknown days after the third dose of vaccination of mRNA-1273. Patient was previously vaccinated with 2 doses of Comirnaty BNT162b2 as primary series (Interchange of vaccine products). The clinical course leading to demise and the cause of death were not reported. It was reported that patient died suddenly a few weeks after the third dose of mRNA-1273 vaccination. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report.
[redacted]		This case was received via United Kingdom MHRA (Reference number: [redacted] on 16-Jun-2022 and was forwarded to Moderna on 16-Jun-2022. .This regulatory authority case was reported by a physician and describes the occurrence of DEATH (Death) in a male patient of an unknown age who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 000088A) for COVID-19 vaccination. . .The patient's past medical history included Chronic lymphatic leukaemia..Concomitant products included TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) from 20-Jan-2021 to 22-Feb-2022 for COVID-19 immunisation.. ..On 13-Jun-2022, the patient received fourth dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. Death occurred on 14-Jun-2022 The patient died on 14-Jun-2022. The cause of death was not reported. It is unknown if an autopsy was performed. . . .The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown.. .For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.. .Patient has not had symptoms associated with COVID-19 not had a COVID-19 test and patient was not enrolled in clinical trial...It was reported that on the evening after the vaccination patient found dead on the floor the following morning.. .Relevant investigations included that the patient will have post mortem...Treatment information was not provided..Company comment:.This regulatory case concerns a male patient of unknown age with medical history of Chronic lymphocytic leukemia, who experienced the unexpected, life-threatening and fatal outcome of Death. The event occurred 1 day after administration of fourth dose of mRNA-1273. Patient was administered with two doses of Pfizer approximately 15 months prior, the interval between the two doses is 33 days. It has been reported that the patient was vaccinated in the evening and was found dead on the floor the following morning. The patient's current medical condition of Chronic lymphocytic leukemia could be a confounder to the event. Details of concomitant medications, medical history, clinical course, treatment and outcome were not provided. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness retained as per Regulatory Authority's report.

Appendix 11.9f Interaction: with Other COVID-19 vaccines (Heterologous Vaccine Schedule): Immunocompromised co-morbidities Dose 3 & 4

Period	medical_history	Case Counts	%
All	COVID-19	290	2%
All	Immunodeficiency	275	2%
All	Diabetes mellitus	135	1%
All	Type 2 diabetes mellitus	86	1%
All	Breast cancer	43	0%
All	Autoimmune thyroiditis	36	0%
All	Neoplasm	36	0%
All	Type 1 diabetes mellitus	29	0%
All	Crohn's disease	25	0%
All	Alcohol use	24	0%
All	Autoimmune disorder	22	0%
All	Chemotherapy	21	0%
All	Neoplasm malignant	18	0%
All	Chronic lymphocytic leukaemia	12	0%
All	Prostate cancer	12	0%
All	Addison's disease	9	0%
All	Benign prostatic hyperplasia	9	0%
All	HIV infection	8	0%
All	Lung neoplasm malignant	8	0%
All	Gastrointestinal carcinoma	7	0%
All	Autoimmune hypothyroidism	6	0%
All	Immunosuppression	6	0%
All	Autonomic nervous system imbalance	5	0%
All	Cancer surgery	5	0%
All	Non-Hodgkin's lymphoma	5	0%
All	Skin cancer	5	0%
All	Uterine leiomyoma	5	0%
All	Bladder cancer	4	0%
All	Colon cancer	4	0%
All	Ovarian cancer	4	0%
All	Alcoholic	3	0%
All	Brain neoplasm	3	0%
All	COVID-19 pneumonia	3	0%
All	Hairy cell leukaemia	3	0%
All	Leukaemia	3	0%
All	Meningioma	3	0%
All	Neurofibromatosis	3	0%
All	Pancreatic carcinoma	3	0%
All	Squamous cell carcinoma	3	0%
All	Thyroid cancer	3	0%
All	Uterine cancer	3	0%
All	Acoustic neuroma	2	0%
All	Cervix carcinoma	2	0%
All	Chronic myeloid leukaemia	2	0%
All	Colorectal adenoma	2	0%
All	Congenital cystic kidney disease	2	0%

Period	medical_history	Case Counts	%
All	Gastric cancer	2	0%
All	Hodgkin's disease	2	0%
All	Immune system disorder	2	0%
All	Immunodeficiency common variable	2	0%
All	Lymphoma	2	0%
All	Oesophageal carcinoma	2	0%
All	Rectal cancer	2	0%
All	Renal cancer	2	0%
All	Testis cancer	2	0%
All	Varicella	2	0%
All	ACICLOVIR	1	0%
All	ACYCLOVIR [ACICLOVIR]	1	0%
All	Acute lymphocytic leukaemia	1	0%
All	Acute myeloid leukaemia	1	0%
All	Alcohol abuse	1	0%
All	Alcohol intolerance	1	0%
All	Alcohol problem	1	0%
All	Alcoholism	1	0%
All	Arnold-Chiari malformation	1	0%
All	Autoimmune hepatitis	1	0%
All	Autoimmune neutropenia	1	0%
All	BRCA2 gene mutation assay	1	0%
All	Basal cell carcinoma	1	0%
All	Benign pleural neoplasm	1	0%
All	Blood immunoglobulin A decreased	1	0%
All	Blood immunoglobulin E increased	1	0%
All	Blood immunoglobulin G decreased	1	0%
All	Blood immunoglobulin M increased	1	0%
All	Brain tumour operation	1	0%
All	Breast cancer female	1	0%
All	Breast cancer in situ	1	0%
All	Breast cancer metastatic	1	0%
All	Bulimia nervosa	1	0%
All	Colorectal cancer	1	0%
All	Colostomy	1	0%
All	Congenital hydrocephalus	1	0%
All	Congenital hypothyroidism	1	0%
All	Desmoid tumour	1	0%
All	Diabetes mellitus inadequate control	1	0%
All	Diabetic nephropathy	1	0%
All	Diabetic retinopathy	1	0%
All	Gallbladder neoplasm	1	0%
All	Gastrointestinal neoplasm	1	0%
All	HER2 positive breast cancer	1	0%
All	Hepatic adenoma	1	0%
All	Hepatocellular carcinomaFH	1	0%

Period	medical_history	Case Counts	%
All	Hormone receptor positive breast canc	1	0%
All	Immune thrombocytopenia	1	0%
All	Immune tolerance induction	1	0%
All	Immunosuppressant drug therapy	1	0%
All	Leukopenia	1	0%
All	Lung adenocarcinoma stage IV	1	0%
All	Lymphocytic leukaemia	1	0%
All	Metastases to liver	1	0%
All	Metastases to lymph nodes	1	0%
All	Metastases to skin	1	0%
All	Phaeochromocytoma	1	0%
All	Pituitary tumour	1	0%
All	Prostate cancer stage III	1	0%
All	Sarcoma	1	0%
All	Selective IgA immunodeficiency	1	0%
All	Throat cancer	1	0%
All	Thymoma	1	0%
All	Vulval cancer	1	0%
Review Period	COVID-19	253	4%
Review Period	Immunodeficiency	92	1%
Review Period	Diabetes mellitus	87	1%
Review Period	Type 2 diabetes mellitus	53	1%
Review Period	Autoimmune thyroiditis	29	0%
Review Period	Alcohol use	24	0%
Review Period	Breast cancer	22	0%
Review Period	Neoplasm	17	0%
Review Period	Autoimmune disorder	14	0%
Review Period	Chemotherapy	12	0%
Review Period	Crohn's disease	12	0%
Review Period	Neoplasm malignant	11	0%
Review Period	Prostate cancer	11	0%
Review Period	Type 1 diabetes mellitus	9	0%
Review Period	Addison's disease	8	0%
Review Period	Chronic lymphocytic leukaemia	8	0%
Review Period	Benign prostatic hyperplasia	7	0%
Review Period	Immunosuppression	6	0%
Review Period	Lung neoplasm malignant	6	0%
Review Period	Colon cancer	4	0%
Review Period	Uterine leiomyoma	4	0%
Review Period	Alcoholic	3	0%
Review Period	Autoimmune hypothyroidism	3	0%
Review Period	Bladder cancer	3	0%
Review Period	HIV infection	3	0%
Review Period	Hairy cell leukaemia	3	0%
Review Period	Non-Hodgkin's lymphoma	3	0%
Review Period	Ovarian cancer	3	0%

Period	medical_history	Case Counts	%
Review Period	Pancreatic carcinoma	3	0%
Review Period	Skin cancer	3	0%
Review Period	Thyroid cancer	3	0%
Review Period	Autonomic nervous system imbalance	2	0%
Review Period	COVID-19 pneumonia	2	0%
Review Period	Gastrointestinal carcinoma	2	0%
Review Period	Hodgkin's disease	2	0%
Review Period	Immune system disorder	2	0%
Review Period	Immunodeficiency common variable	2	0%
Review Period	Lymphoma	2	0%
Review Period	Neurofibromatosis	2	0%
Review Period	Uterine cancer	2	0%
Review Period	Varicella	2	0%
Review Period	ACYCLOVIR [ACICLOVIR]	1	0%
Review Period	Alcohol abuse	1	0%
Review Period	Alcohol intolerance	1	0%
Review Period	Alcohol problem	1	0%
Review Period	Alcoholism	1	0%
Review Period	Autoimmune hepatitis	1	0%
Review Period	Autoimmune neutropenia	1	0%
Review Period	BRCA2 gene mutation assay	1	0%
Review Period	Benign pleural neoplasm	1	0%
Review Period	Blood immunoglobulin A decreased	1	0%
Review Period	Blood immunoglobulin E increased	1	0%
Review Period	Blood immunoglobulin G decreased	1	0%
Review Period	Blood immunoglobulin M increased	1	0%
Review Period	Breast cancer female	1	0%
Review Period	Breast cancer metastatic	1	0%
Review Period	Cancer surgery	1	0%
Review Period	Cervix carcinoma	1	0%
Review Period	Chronic myeloid leukaemia	1	0%
Review Period	Colorectal adenoma	1	0%
Review Period	Colorectal cancer	1	0%
Review Period	Colostomy	1	0%
Review Period	Diabetes mellitus inadequate control	1	0%
Review Period	Diabetic nephropathy	1	0%
Review Period	Diabetic retinopathy	1	0%
Review Period	Gallbladder neoplasm	1	0%
Review Period	Gastric cancer	1	0%
Review Period	Gastrointestinal neoplasm	1	0%
Review Period	HER2 positive breast cancer	1	0%
Review Period	Hepatic adenoma	1	0%
Review Period	Hepatocellular carcinomaFH	1	0%
Review Period	Hormone receptor positive breast canc	1	0%
Review Period	Immune thrombocytopenia	1	0%
Review Period	Immune tolerance induction	1	0%

Period	medical_history	Case Counts	%
Review Period	Immunosuppressant drug therapy	1	0%
Review Period	Leukaemia	1	0%
Review Period	Leukopenia	1	0%
Review Period	Lung adenocarcinoma stage IV	1	0%
Review Period	Lymphocytic leukaemia	1	0%
Review Period	Meningioma	1	0%
Review Period	Metastases to liver	1	0%
Review Period	Metastases to lymph nodes	1	0%
Review Period	Metastases to skin	1	0%
Review Period	Oesophageal carcinoma	1	0%
Review Period	Prostate cancer stage III	1	0%
Review Period	Rectal cancer	1	0%
Review Period	Renal cancer	1	0%
Review Period	Sarcoma	1	0%
Review Period	Squamous cell carcinoma	1	0%
Review Period	Testis cancer	1	0%
Review Period	Throat cancer	1	0%
Review Period	Thymoma	1	0%
Review Period	Vulval cancer	1	0%
		2,062	

Appendix 11.10 Use in frail subjects: Fatal cases: Case Listings and Case Narratives-RP

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
[redacted]	THAILAND	Ill-defined disorder, Myocardial infarction	63.00	Female	Hypertension(C); Diabetes mellitus(C); Cardiac disorder(C)	0	This case was received via Zuellig Pharma (Reference number: [redacted] on 10-Jan-2022 and was forwarded to Moderna on 11-Jan-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of ILL-DEFINED DISORDER (Other ill-defined and unspecied causes of mortality) and MYOCARDIAL INFARCTION (Myocardial Infarction) in a 63-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. TRC049F21A) for an unknown indication. Concurrent medical conditions included Hypertension, Diabetes and Heart disease, unspecified. On 14-Dec-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On 15-Dec-2021, the patient experienced ILL-DEFINED DISORDER (Other ill-defined and unspecied causes of mortality) (seriousness criterion death) and MYOCARDIAL INFARCTION (Myocardial Infarction) (seriousness criterion death). The patient died on 15-Dec-2021. The reported cause of death was Myocardial infarction and other ill-defined and unspecified causes of mortality. An autopsy was performed, but no results were provided. For mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown), the reporter did not provide any causality assessments. Company Comment: This is a regulatory case concerning a 63-year-old female patient with medical history of diabetes mellitus, hypertension and cardiac disorder, who experienced the serious unexpected fatal AESI event of myocardial infarction and serious unexpected fatal event of ill-defined disorder. The events occurred on the next day after the first dose of mRNA-1273 vaccine administration. The events were assessed as related to the product administration. The rechallenge was not applicable due to the event outcome. The medical history of diabetes mellitus, hypertension and cardiac disorder considered as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. 1 day after vaccination, her condition was normal. On 15/12/21 at 05:00 pm, the relative found her lying on her back, unconscious, pale and cold. Therefore, she was taken to the hospital. On 15/12/21 at 06:06 pm, the relative infirmed the vaccine recipient's history of vaccination with Moderna 1 injection on 14/12/21, the condition after vaccination was normal. 1 hr PTA (at 05:00 pm), the relative found the vaccine recipient lying on her back, unconcious, pale and cold. Therefore, she was taken to the hospital Symptoms after injection, usually 1 hour before coming (05:00 p.m.) found the patient lying on his back. Called unconscious, pale and cold, so he was taken to the hospital (LWS at 04:00 pm). BP=- mmhg. P=-/min R=-/min , T=- C0 , At ER	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							NO HR DTX=401 mg% ,O2sat=60% EKG monitor - asystole start CPR , At 06:00 pm, on ETT no 7.5 mark 22 on 0.9% NSS IV load. At 06:05 pm, the hospital ordered AdreN/Aline 1 amp IV q 4 min start at 06:05 pm, 7 dose N/AHCO3 100 cc IV push. At 06:06 pm, N/AHCO3 100 cc IV drip. At 06:15 pm, confirmed death at 06:30 pm. Assessment of cause of death from myocardial infarction. The relative suspected the cause of death. The vaccine recipient received Moderna vaccine on 14/12/21, ATK=Negative. The GP physician consult the physician staff for PCR and will notify the physician staff again when receive the result of PCR for autopsy. Diagnosis from the physician was Other ill-defined and unspecied causes of mortality and still waiting the result for autopsy at the hospital.	
[redacted]	HUNGARY	Cardiogenic shock	65.00	Male	Emphysema(H); Arteriosclerosis(H); Cirrhosis alcoholic(H); Cardiomyopathy alcoholic(H); Alcoholism(H)	0	This regulatory authority case was reported by a physician and describes the occurrence of CARDIOGENIC SHOCK (Cardiogenic shock) in a 65-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3003659) for COVID-19 vaccination. The patient's past medical history included Emphysema, Arteriosclerosis, Alcoholic cirrhosis, Alcoholic cardiomyopathy and Chronic alcoholism. On 19-Nov-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .5 ml. On 28-Nov-2021, after starting mRNA-1273 (Spikevax), the patient experienced CARDIOGENIC SHOCK (Cardiogenic shock) (seriousness criteria death and medically significant). The patient died on 28-Nov-2021. An autopsy was performed. The autopsy-determined cause of death was Cardiogenic shock. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. The patient was died suddenly 9 days after vaccination with Spikevax. No concomitant medications were provided by the reporter. No treatment information was provided by the reporter. This is a regulatory authority case concerning a 65-year-old, male patient with medical history of Emphysema, Arteriosclerosis, Alcoholic cirrhosis, Alcoholic cardiomyopath, who experienced the unexpected fatal event of Cardiogenic Shock, which resulted in death. The events occurred approximately 9 days after the unknown dose of mRNA-1273 COVID 19 Vaccine. The rechallenge was not applicable, as information about further dosing was not disclosed. An autopsy determined the casuse of death is Cardiogenic shock. The medical history of Emphysema, Arteriosclerosis, Alcoholic cirrhosis, Alcoholic cardiomyopathy remains a confounder.The benefit-risk relationship of mRNA-1273 COVID 19 Vaccine, is not affected by this report.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
[redacted]	AUSTRIA	Acute myocardial infarction, Brain herniation, Brain oedema, Cardiac arrest, Ventricular fibrillation	57.00	Male	Pneumothorax spontaneous(H); COVID-19(H); Coronary artery disease(C)	0	This case was received via European Medicines Agency (Reference number:[redacted] on 03-Jan-2022 and was forwarded to Moderna on 03-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of CARDIAC ARREST (cardiovascular arrest), VENTRICULAR FIBRILLATION (stemi/ventricular fibrillation in pre-existing 2-vascular disease), BRAIN OEDEMA (generalis. cerebral edema), ACUTE MYOCARDIAL INFARCTION (stemi/ventricular fibrillation in pre-existing 2-vascular disease) and BRAIN HERNIATION (transforaminellen Herniation) in a 57-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004670) for COVID-19 vaccination. The patient's past medical history included Pneumothorax spontaneous in January 2021 and COVID-19 in November 2020. Concurrent medical conditions included Double vessel disease. On 07-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 10-Dec-2021, the patient experienced VENTRICULAR FIBRILLATION (stemi/ventricular fibrillation in pre-existing 2-vascular disease) (seriousness criterion death) and ACUTE MYOCARDIAL INFARCTION (stemi/ventricular fibrillation in pre-existing 2-vascular disease) (seriousness criterion death). On 13-Dec-2021, the patient experienced CARDIAC ARREST (cardiovascular arrest) (seriousness criterion death), BRAIN OEDEMA (generalis. cerebral edema) (seriousness criterion death) and BRAIN HERNIATION (transforaminellen Herniation) (seriousness criterion death). The patient died on 13-Dec-2021. The reported cause of death was Brain edema, Cerebellar tonsillar herniation and Cardiac arrest. An autopsy was performed, but no results were provided. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 10-Dec-2021, Angiocardiogram: abnormal (abnormal) 1st coronary 2-vessel disease with functional proximal LAD occlusion, 90% stenosis of an IMED and 70% stenosis of a small second margin palace. 2. Successful LAD-PCI with implantation of an DES (Ultimaster Tansei 3.0 x 28 m) with good primary result. 3. Successful IMED direct stenting with an DES (Xience Sierra 2.25x18mm) with good primary result. 4. Successful installation of a CVC on the right femoral.. On 13-Dec-2021, Computerised tomogram head: abnormal (abnormal) Image of generalized cerebral edema as part of hypoxic brain damage in contrast medium filled sinuses in e.g. coronary angiography and resuscitation. No longer delineate the basal cisterns. Completely missing bark-marrow differentiation.. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered CARDIAC ARREST (cardiovascular arrest), VENTRICULAR FIBRILLATION (stemi/ventricular fibrillation in pre-existing 2-vascular disease), BRAIN OEDEMA (generalis.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							cerebral edema), ACUTE MYOCARDIAL INFARCTION (stemi/ventricular fibrillation in pre-existing 2-vascular disease) and BRAIN HERNIATION (transforaminellen Herniation) to be unlikely related. No relevant concomitant medications were reported. Treatment drug information was not provided. This fatal regulatory case concerns a 57-year-old, male patient with medical history of Pneumothorax spontaneous, Double vessel disease and COVID-19 who experienced the unexpected fatal events of ACUTE MYOCARDIAL INFARCTION (AESI), VENTRICULAR FIBRILLATION(AESI), CARDIAC ARREST, BRAIN OEDEMA and BRAIN HERNIATION The event occurred 4 days after 3rd dose of Moderna Covid 19 vaccine. The reported cause of death (12/23/2021) was Cardiac arrest. It is unknown if an autopsy was performed. The rechallenge is not applicable The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event terms, seriousness and onset dates were captured as provided by the regulatory Authority Most recent FOLLOW-UP information incorporated above includes: On 03-Jan-2022: Due to incorrect follow-up receipt date, this case is amended to reflect the actual follow-up receipt date/Date FU Rcvd by Safety. This case was submitted on-time based on the actual follow-up receipt date. The actual follow-up receipt date/ Date FU Rcvd by Safety for this case is 03-Jan-2022. On 05-Jan-2022: Follow up received wherein updated death date, cause of death, new events, reporter causality and lab data.	
[redacted]	UNITED KINGDOM	Cardiac arrest, Deep vein thrombosis, Haematochezia, Pain in extremity, Pulmonary thrombosis, Transient ischaemic attack	63.00	Female	Vascular dementia(C); Steroid therapy; Colostomy	COVID-19 VACCINE ASTRAZENECA; COVID-19 VACCINE ASTRAZENECA; ASPIRIN [ACETYLSALICYLIC ACID]; CETIRIZINE HYDROCHLORIDE; LISINOPRIL; LEVOTHYROXINE; MEMANTINE; DONEPEZIL HYDROCHLORIDE	This case was initially received via United Kingdom MHRA (Reference number [redacted] on 05-Jan-2022. The most recent information was received on 06-Feb-2022 and was forwarded to Moderna on 06-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of PULMONARY THROMBOSIS (pulmonary thrombosis), TRANSIENT ISCHAEMIC ATTACK (TIA), DEEP VEIN THROMBOSIS (DVT), CARDIAC ARREST (Cardiac arrest), HAEMATOCHEZIA (Blood in stool) and PAIN IN EXTREMITY (Leg pain) in a 63-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3004675) for COVID-19 vaccination. The patient's past medical history included Steroid therapy (Taking regular steroid treatment (e.g. orally or rectally)) and Colostomy. Concurrent medical conditions included Vascular dementia (Treatment for Vascular Dementia). Concomitant products included COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) from 24-Feb-2021 to 19-May-2021 and	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) from 24-Feb-2021 to an unknown date for COVID-19 vaccination, MEMANTINE and DONEPEZIL HYDROCHLORIDE for Vascular dementia, ASPIRIN [ACETYLSALICYLIC ACID], CETIRIZINE HYDROCHLORIDE, LISINOPRIL and LEVOTHYROXINE for an unknown indication. On 24-Nov-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 15-Nov-2021, the patient experienced HAEMATOCHEZIA (Blood in stool) (seriousness criteria hospitalization, disability and medically significant) and PAIN IN EXTREMITY (Leg pain) (seriousness criteria hospitalization, disability and medically significant). On 25-Nov-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced TRANSIENT ISCHAEMIC ATTACK (TIA) (seriousness criteria hospitalization, disability and medically significant). On 15-Dec-2021, the patient experienced DEEP VEIN THROMBOSIS (DVT) (seriousness criteria hospitalization, disability and medically significant). On an unknown date, the patient experienced PULMONARY THROMBOSIS (pulmonary thrombosis) (seriousness criteria hospitalization, disability and medically significant) and CARDIAC ARREST (Cardiac arrest) (seriousness criteria death, hospitalization, disability and medically significant). On 29-Nov-2021, TRANSIENT ISCHAEMIC ATTACK (TIA) had resolved. The patient died on 15-Dec-2021. The reported cause of death was Cardiac arrest. An autopsy was performed. The autopsy-determined cause of death was Pulmonary thromboembolism and Thrombosis venous deep. At the time of death, PULMONARY THROMBOSIS (pulmonary thrombosis), DEEP VEIN THROMBOSIS (DVT), HAEMATOCHEZIA (Blood in stool) and PAIN IN EXTREMITY (Leg pain) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test. On an unknown date, Scan: not reported not reported and not reported not reported. Patient not had symptoms associated with COVID-19. Hospital said TIA but second scan showed different. Patient died 10 days later from deep vein thrombosis (DVT) clot and pulmonary thrombosis (heart attack). Patient had not tested positive for COVID-19 since had the vaccine. Company Comment: This is a regulatory case concerning a 63 year-old, female patient with a history of vascular dementia, polypharmacy and Interchange of vaccine products (vaccination	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							with two doses of COVID-19 vaccine AstraZeneca approximately 6 months prior), who experienced the serious Fatal unexpected, event of cardiac arrest and the serious unexpected AESI of Pulmonary thrombosis, Transient ischaemic attack and Deep vein thrombosis. The event Transient ischaemic attack occurred approximately 1 day after the booster dose of mRNA-1273 vaccine, the patient was admitted to the hospital and was after discharged, the event was reported as recovered. The events Deep vein thrombosis and cardiac arrest occurred approximately 21 days after the booster dose of mRNA-1273 vaccine (the day the patient died) and the event Pulmonary thrombosis on an unknown date. The rechallenge was not applicable due to the fatal outcome. The patient died 21 days after receiving the booster dose of mRNA-1273 vaccine, the reported cause of death by the regulatory authority was cardiac arrest, it is unknown whether an autopsy was performed. The reporter states that the death certificate provides as causes of death Pulmonary thrombosis, and Deep vein thrombosis. The medical history, of vascular dementia and polypharmacy suggests unreported, unspecified cardiovascular disorder which could remain as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 06-Feb-2022: Follow-up Received - Medical history (Colostomy) added, relevant history updated, Lab test (Scan) added, Autopsy result added, Dose details added for concomitant drug, event (Pain in extremity, Haematochezia) added.	
[redacted]	SWITZERLAND	COVID-19, Diarrhoea, Dyspnoea, Oxygen saturation decreased, Vaccination failure	86.00	Female	Asthma(C); Myocardial ischaemia(C); Hypertension(C); Hypothyroidism(C); Small cell lung cancer(C)	CLOPIDOGREL; ESOMEPRAZOLE; EUTHYROX; LISINOPRIL; NEBILET; ZOLPIDEM; SERETIDE; LAXOBERON; PURSANA; ATOZET; KALCIPOS D3; LERCANIDIPINE; FLUIMUCIL; DOMPERIDONE; CO-DAFALGAN; TRAMADOL	This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 05-Jan-2022 and was forwarded to Moderna on 05-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of VACCINATION FAILURE (Infection despite vaccination), DIARRHOEA (Watery diarrhoea), DYSPNOEA (Dyspnea), OXYGEN SATURATION DECREASED (Desaturation) and COVID-19 (SARS-CoV-2 infection) in an 86-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. Concurrent medical conditions included Asthma, Ischemic heart disease, Hypertension arterial, Hypothyroidism (substituted) and Small cell carcinoma of the lung. Concomitant products included CLOPIDOGREL, ESOMEPRAZOLE, LEVOTHYROXINE SODIUM (EUTHYROX), LISINOPRIL, NEBIVOLOL HYDROCHLORIDE (NEBILET), ZOLPIDEM, FLUTICASONE PROPIONATE, SALMETEROL XINAFOATE (SERETIDE), SODIUM PICOSULFATE (LAXOBERON), FICUS CARICA EXTRACT, SORBITOL (PURSANA), ATORVASTATIN CALCIUM, EZETIMIBE (ATOZET), CALCIUM CARBONATE, COLECALCIFEROL (KALCIPOS D3), LERCANIDIPINE, ACETYLCYSTEINE (FLUIMUCIL), DOMPERIDONE, CODEINE PHOSPHATE HEMIHYDRATE,	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							PARACETAMOL (CO-DAFALGAN) and TRAMADOL for an unknown indication. On 12-Feb-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 18-Mar-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 19-Nov-2021, the patient experienced VACCINATION FAILURE (Infection despite vaccination) (seriousness criteria death, hospitalization and medically significant), DIARRHOEA (Watery diarrhoea) (seriousness criteria death, hospitalization and medically significant), DYSPNOEA (Dyspnea) (seriousness criteria death, hospitalization and medically significant), OXYGEN SATURATION DECREASED (Desaturation) (seriousness criteria death, hospitalization and medically significant) and COVID-19 (SARS-CoV-2 infection) (seriousness criteria death, hospitalization and medically significant). The patient died on 28-Nov-2021. The reported cause of death was infection despite vaccination, SARS-CoV-2 infection, Watery diarrhoea, Dyspnea and desaturation. An autopsy was not performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 22-Nov-2021, SARS-CoV-2 test: positive (Positive) Positive. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered VACCINATION FAILURE (Infection despite vaccination), DIARRHOEA (Watery diarrhoea), DYSPNOEA (Dyspnea), OXYGEN SATURATION DECREASED (Desaturation) and COVID-19 (SARS-CoV-2 infection) to be possibly related. It was verbally reported that, dyspnea with desaturation as of 22 November. She was hospitalized on 26.11.2021. In continuous care, treatment of dexamethasone and tocilizumab was introduced. The evolution was unfavorable. This patient experienced SARS-CoV-2 infection approximately 8 months after the second injection of Spikevax Moderna vaccine. The Phase 3 study that allowed the registration of the COVID-19 Vaccine Moderna® vaccine included approximately 30,000 people and showed 94% efficacy of the vaccine, based on the number of symptomatic COVID-19 infections reported in each group; 11 out of 14'134 vaccine cases versus 185 cases out of 14,073 placebo (1). The final analysis of this study demonstrated an overall effectiveness in the prevention of COVID-19 disease of 93.2%. The effectiveness in the prevention of severe disease was 98.2%, and the effectiveness in the prevention of asymptomatic infection starting 14 days after the second injection was 63%. In addition, vaccine effectiveness was consistent across all ethnic and racial groups, age groups and participants with co-morbidities such as chronic lung disease, heart disease, obesity, diabetes, liver failure, or HIV (2). In studies conducted in “real life”, high	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							efficacy of more than 90% was also observed after the second dose (3.4). Company Comment - This regulatory authority case concerns an 86 year old female patient with medical history of hypothyroidism and small cell carcinoma of the lung who experienced the serious unexpected events of vaccination failure, diarrhea, dyspnea, oxygen saturation decreased and COVID-19. The events occurred approximately 8 months after the second dose of mRNA-1273 vaccine, and the outcome was fatal, with death occurring 9 days later. The reported causes of death were infection despite vaccination, SARS-CoV-2 infection, diarrhoea, dyspnea and desaturation. Patient's medical history of hypothyroidism and small cell carcinoma of the lung remains a confounder. The rechal	
[redacted]	SWITZERLAND	Apnoea, Cardiac arrest	86.00	Male	Pulmonary fibrosis(C); Myocardial infarction(H)	0	This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 05-Jan-2022 and was forwarded to Moderna on 05-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of CARDIAC ARREST (respiratory arrest and cardiac arrest, unsuccessful resuscitation) and APNOEA (respiratory arrest and cardiac arrest, unsuccessful resuscitation) in an 86-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. The patient's past medical history included Myocardial infarction (The patient has had several heart attacks in the past.). Concurrent medical conditions included Lung fibrosis (The patient suffered from pre-existing chronic progressive pulmonary fibrosis.). On 30-Nov-2021, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 50 µg. On 30-Nov-2021 at 12:05 PM, the patient experienced CARDIAC ARREST (respiratory arrest and cardiac arrest, unsuccessful resuscitation) (seriousness criterion death) and APNOEA (respiratory arrest and cardiac arrest, unsuccessful resuscitation) (seriousness criterion death). The patient died on 30-Nov-2021. The cause of death was not reported. It is unknown if an autopsy was performed. The autopsy-determined cause of death was Death from natural causes. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered CARDIAC ARREST (respiratory arrest and cardiac arrest, unsuccessful resuscitation) and APNOEA (respiratory arrest and cardiac arrest, unsuccessful resuscitation) to be possibly related. Treatment information not provided. Concomitant medication not provided. The patient stopped breathing on car after taking of 50 mcg of Spikevax booster vaccination (Elasomeran, lot number unknown)	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							on 30-Nov-2021 at 11:45 a.m. As per the autopsy the patient died of natural death findings by the forensic medicine institute. The Patient had pre-existing chronic progressive pulmonary fibrosis, take oxygen therapy and several heart attacks in the past. Therapy include oxygen therapy for pulmonary fibrosis. Company comment: This Regulatory authority case concerns a 86-year-old, male patient, with medical history of lung fibrosis and myocardial infarction, who experienced the unexpected, serious (fatal) event of apnoea and cardiac arrest. The patient received a dose of mRNA-1273 vaccine, considered as the third dose of the patient's COVID-19 vaccination schedule. It was reported that the patient was vaccinated at 11:45am and after 20 minutes of monitoring, he went to the car on foot independently, however, when the patient was sitting in the car, his son noticed that the patient stopped breathing. Despite immediate resuscitation by doctors, the patient was pronounced dead at 12:15pm, approximately 30 minutes after vaccination. According to the autopsy findings of the forensic medicine institute, the patient died of natural death. The patient suffered from pre-existing chronic progressive pulmonary fibrosis with home oxygen therapy and had several myocardial infarctions in the past. The medical history of lung fibrosis and myocardial infarction remain as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	
[redacted]	GERMANY	Sudden death	85.00	Female	Myocardial ischaemia(H); Chronic obstructive pulmonary disease(H)	0	This case was received via European Medicines Agency (Reference number: [redacted] on 05-Jan-2022 and was forwarded to Moderna on 05-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of SUDDEN DEATH (Sudden death unexplained) in an 85-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Chronic ischaemic heart disease, unspecified and COPD. On 09-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. The cause of death was not reported. An autopsy was performed, but no results were provided. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were provided by the reporter. No treatment information was provided by the reporter. It was reported that patient died 3 days after vaccination, autopsy result not reported. Company comment: This is a regulatory case concerning a 85-year-old, female patient with a history of Myocardial ischaemia and Chronic obstructive pulmonary disease, who experienced the Fatal unexpected , according CCDS, event of Sudden death. The event occurred approximately 3 days after the booster dose of mRNA-1273 vaccine. Cause of death was not further specified;	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							autopsy result not reported. The rechallenge was not applicable due to the fatal outcome. The medical history of Myocardial ischaemia and Chronic obstructive pulmonary disease remain as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 05-Jan-2022: Follow up received wherein suspect product indication updated On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 04-Jan-2022.	
[redacted]	BRUNEI DARUSSALAM	Asthenia, Back pain, Death, Decreased appetite, Pyrexia, Sepsis	79.00	Female	Hypertension(C); Diabetes mellitus(C); Back pain(C); Osteoporosis(C); Hypercalcaemia(C); Hyperlipidaemia(C); Oedema(H); Anaemia folate deficiency(H)	0	This regulatory authority case was reported by an other health care professional and describes the occurrence of SEPSIS (Sepsis), ASTHENIA (body weakness), DECREASED APPETITE (loss of appetite), BACK PAIN (back pain), PYREXIA (fever) and DEATH (Death) in a 79-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (batch no. 3004736) for COVID-19 vaccination. The patient's past medical history included Oedema and Folate deficiency anaemia. Concurrent medical conditions included Hypertension, Diabetes (Diabetes tightly controlled.), Chronic back pain (Chronic low back pain with hypercalcemia.), Osteoporosis, Hypercalcaemia (Chronic low back pain with hypercalcemia.) and Hyperlipidaemia (Hyperlipidemia dietary controlled.). On 05-Sep-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (Intramuscular) 1 dosage form. On 09-Sep-2021, the patient experienced SEPSIS (Sepsis) (seriousness criterion death). On an unknown date, the patient experienced ASTHENIA (body weakness) (seriousness criterion death), DECREASED APPETITE (loss of appetite) (seriousness criterion death), BACK PAIN (back pain) (seriousness criterion death) and PYREXIA (fever) (seriousness criterion death). The patient died on 14-Sep-2021. The reported cause of death was Sepsis, body weakness, loss of appetite, Fever and Back pain. An autopsy was not performed. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications were not reported.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							Treatment medications were not reported. Time of vaccination include 12:59 PM. Company Comment include This case concerns a 79-year-old female patient with a relevant medical history of Hypertension, Hyperlipidemia, and Diabetes, who experienced the serious unexpected events of Sepsis, Asthenia, Decreased Appetite, Back Pain, Pyrexia, and Death. The event of Sepsis occurred 4 days after the first dose of mRNA-1273 vaccine, while the events of Asthenia, Decreased Appetite, Back Pain, Pyrexia occurred on an unspecified date after the first dose of mRNA-1273 vaccine, with death occurring 9 days after the administration of mRNA-1273 vaccine. The patient's medical history of Hypertension, Hyperlipidemia, and Diabetes are confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting as Death and retained for consistency with the RA report.	
[redacted]	BRUNEI DARUSSALAM	Acute myocardial infarction, Death, Dyspnoea, Hypervolaemia	54.00	Male	Type 2 diabetes mellitus(C); Nephropathy(C); Myocardial ischaemia(H); Hypertension(C); Hyperlipidaemia(C); Hyperuricaemia(H); Ex-tobacco user(H); Obesity(C)	LINAGLIPTIN; INSULIN ISOPHANE; ALLOPURINOL; AQUEOUS BP; ASPIRIN EC; CALCIUM CARBONATE; CARVEDILOL; DOXAZOSIN; EZETIMIBE; FUROSEMIDE; LORATADINE; LOSARTAN; ROSUVASTATIN; OMEPRAZOLE; NIFEDIPINE; CALCITRIOL; EPOETIN BETA	This regulatory authority case was reported by an other health care professional and describes the occurrence of ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction), HYPERVOLAEMIA (fluid overload), DYSPNOEA (severe shortness of breath) and DEATH (unresponsive and death) in a 54-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (batch no. 3004736) for an unknown indication. The patient's past medical history included Ischaemic heart disease in 2014, Hyperuricaemia and Ex-smoker. Concurrent medical conditions included Type 2 diabetes mellitus, Renal disease, Hypertension, Hyperlipidaemia and Obesity. Concomitant products included LINAGLIPTIN from 03-Jun-2021 to 03-Jun-2021, INSULIN ISOPHANE BOVINE (INSULIN ISOPHANE) from 03-Jun-2021 to 03-Jun-2021, ALLOPURINOL from 26-Oct-2021 to 26-Oct-2021, EMULSIFYING WAX, PARAFFIN, LIQUID, WHITE SOFT PARAFFIN (AQUEOUS BP) from 26-Oct-2021 to 26-Oct-2021, ACETYLSALICYLIC ACID (ASPIRIN EC) from 26-Oct-2021 to 26-Oct-2021, CALCIUM CARBONATE from 26-Oct-2021 to 26-Oct-2021, CARVEDILOL from 26-Oct-2021 to 26-Oct-2021, DOXAZOSIN from 26-Oct-2021 to 26-Oct-2021, EZETIMIBE from 26-Oct-2021 to 26-Oct-2021, FUROSEMIDE from 26-Oct-2021 to 26-Oct-2021, LORATADINE from 26-Oct-2021 to 26-Oct-2021, LOSARTAN from 26-Oct-2021 to 26-Oct-2021, ROSUVASTATIN from 26-Oct-2021 to 26-Oct-2021, OMEPRAZOLE from 26-Oct-2021 to 26-Oct-2021, NIFEDIPINE from 26-Oct-2021 to 26-Oct-2021, CALCITRIOL from 26-Oct-2021 to 26-Oct-2021 and EPOETIN BETA from 26-Oct-2021 to 26-Oct-2021 for an unknown indication. On 26-Oct-2021 at 9:49 AM, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (Intramuscular) 1 dosage form. On 27-Oct-2021 at 7:21 AM, the patient experienced ACUTE MYOCARDIAL	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							INFARCTION (Acute myocardial infarction) (seriousness criterion death), HYPERVOLAEMIA (fluid overload) (seriousness criterion death), DYSPNOEA (severe shortness of breath) (seriousness criterion death) and DEATH (unresponsive and death) (seriousness criterion death). An autopsy was not performed. For mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (Intramuscular), the reporter did not provide any causality assessments. No Treatment Medication reported. Patent mentioned he had PTBt in 2018. Company Comment This case concerns a 54-year-old male patient with a relevant medical history of Type 2 diabetes mellitus, Renal disease, Hypertension, Hyperlipidaemia and Obesity, who experienced the serious unexpected AESI of Acute Myocardial Infarction, and the serious unexpected events Hypervolaemia, Dyspnoea and Death. The events occurred 21 hours and 32 mins days after the second dose of mRNA-1273 vaccine. The medical history of Type 2 diabetes mellitus, Renal disease, Hypertension, Hyperlipidaemia and Obesity are confounders. No autopsy was reported. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting as death and retained for consistency with the RA report.	
[redacted]	BRUNEI DARUSSALAM	Asthenia, Illness, Malaise	29.00	Male	Diabetes mellitus(C); Burkholderia pseudomallei infection(H); Tobacco user(C)	DICLOFENAC SODIUM; EUGENOL;MENTHOL; METHYL SALICYLATE; ORPHENADRINE;PARACETAMOL; OMEPRAZOLE; MULTIVITAMIN [VITAMINS NOS]	This regulatory authority case was reported by an other health care professional and describes the occurrence of MALAISE (Not feeling well, but becoming more sick, not taking orally well and weak), ILLNESS (Not feeling well, but becoming more sick, not taking orally well and weak) and ASTHENIA (Not feeling well, but becoming more sick, not taking orally well and weak) in a 29-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (batch no. 3004736) for an unknown indication. The patient's past medical history included Melioidosis (Melioidosis (right arm) in 2020) in 2020. Concurrent medical conditions included Diabetes mellitus (Newly diagnosed diabetes mellitus in 2020) since 2020 and Smoker (Smoker I pack year). Concomitant products included DICLOFENAC SODIUM from 25-Oct-2021 to an unknown date, EUGENOL;MENTHOL;METHYL SALICYLATE from 25-Oct-2021 to an unknown date, ORPHENADRINE;PARACETAMOL from 25-Oct-2021 to an unknown date, OMEPRAZOLE from 25-Oct-2021 to an unknown date and MULTIVITAMIN [VITAMINS NOS] from 25-Oct-2021 to an unknown date for an unknown indication.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							On 30-Aug-2021 at 6:32 AM, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (Intramuscular) 1 dosage form. On 21-Oct-2021, the patient experienced MALAISE (Not feeling well, but becoming more sick, not taking orally well and weak) (seriousness criterion death). On an unknown date, the patient experienced ILLNESS (Not feeling well, but becoming more sick, not taking orally well and weak) (seriousness criterion death) and ASTHENIA (Not feeling well, but becoming more sick, not taking orally well and weak) (seriousness criterion death). The patient died on 27-Oct-2021. An autopsy was not performed. For mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (Intramuscular), the reporter did not provide any causality assessments. On 27-Oct-2021 the other HCP reported that the patient was notified and weight information was not available. The concomitant medication was given as Antacid liquid 10mls TDS administered on 25-10-2021. No treatment medication details was provided. Company Comment : This is a spontaneous case concerning a 29-year-old male patient with medical history of diabetes mellitus and Burkholderia pseudomallei infection, who experienced the serious fatal unexpected events of malaise, illness and asthenia. The events occurred 1 month 21 days after the second dose of mRNA-1273 vaccine administration. The events were assessed as related to the product administration. The rechallenge was not applicable since the events occurred after the second dose and no further dosing is expected. The medical history of diabetes mellitus and Burkholderia pseudomallei infection considered as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	
[redacted]	BRUNEI DARUSSALAM	Myocardial infarction	53.00	Male	Type 2 diabetes mellitus(C)	0	This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 06-Jan-2022 and was forwarded to Moderna on 06-Jan-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDIAL INFARCTION (Myocardial infarction) in a 53-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (batch no. 3004668) for an unknown indication. Concurrent medical conditions included Type 2 diabetes mellitus. On 25-Jul-2021 at 9:56 AM, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (Intramuscular) 1 dosage form. On 29-Jul-2021 at 6:59 PM, the patient experienced MYOCARDIAL INFARCTION (Myocardial infarction) (seriousness criteria death and medically significant). An autopsy was not performed.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							For mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication provided. No treatment information mentioned. Company Comment: This case refers to a 53-year-old male patient with no relevant medical history who experienced the unexpected event of Myocardial infarction approximately 4 days after the first dose of mRNA-1273 vaccine. No causality assessment was provided by the reporter. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events seriousness assessed as per Regulatory Authority reporting.	
[redacted]	BRUNEI DARUSSALAM	Acute myocardial infarction, Cardiac arrest	52.00	Male	End stage renal disease(C); Diabetes mellitus(C); Coronary artery disease(C); Cerebrovascular accident(H)	HYDRALAZINE HYDROCHLORIDE; SENNA [SENNA ALEXANDRINA LEAF]; LACTULOSE; ATORVASTATIN; LINAGLIPTIN; CALCIUM CARBONATE; AMLODIPINE; IRBESARTAN; OMEPRAZOLE; CLOPIDOGREL; ASPIRIN EC; BISOPROLOL; DUTASTERIDE AND TAMSULOSIN HCL; EPOETIN BETA; CALAMINE	This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 06-Jan-2022 and was forwarded to Moderna on 06-Jan-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction) and CARDIAC ARREST (Cardiac arrest) in a 52-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (batch no. 3003184) for an unknown indication. The patient's past medical history included Stroke. Concurrent medical conditions included End stage renal disease, Diabetes mellitus and Coronary artery disease. Concomitant products included HYDRALAZINE HYDROCHLORIDE, SENNA ALEXANDRINA LEAF (SENNA [SENNA ALEXANDRINA LEAF]), LACTULOSE, ATORVASTATIN, LINAGLIPTIN, CALCIUM CARBONATE, AMLODIPINE, IRBESARTAN, OMEPRAZOLE, CLOPIDOGREL, ACETYLSALICYLIC ACID (ASPIRIN EC), BISOPROLOL, DUTASTERIDE, TAMSULOSIN HYDROCHLORIDE (DUTASTERIDE AND TAMSULOSIN HCL), EPOETIN BETA and CALAMINE for an unknown indication. On 01-Jul-2011 at 2:34 PM, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (Intramuscular) 1 dosage form. On 07-Jul-2021 at 9:20 AM, the patient experienced ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction) (seriousness criteria death and medically significant) and CARDIAC ARREST (Cardiac arrest) (seriousness criteria death and medically significant). An autopsy was not performed. For mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (Intramuscular), the reporter did not provide any causality assessments.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							Treatment medications was not reported. Company Comment: This case concerns a 52 year-old male patient with a history of end-stage renal disease, diabetes mellitus, coronary artery disease and stroke who experienced the unexpected serious adverse events of special interest of acute myocardial infarction and the unexpected serious event of cardiac arrest which occurred 6 days after the first dose of mRNA-1273 vaccine and had a fatal outcome. The medical history of end-stage renal disease, diabetes mellitus, coronary artery disease and stroke remain confounders for the events. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness assessed as per Regulatory Authority reporting.	
[redacted]	BRUNEI DARUSSALAM	Myocardial infarction	54.00	Male	Coronary angioplasty; Type 2 diabetes mellitus(C); Hyperlipidaemia(C)	CLOPIDOGREL; ASPIRIN (E.C.); ISOSORBIDE MONONITRATE; ACARBOSE; GLICLAZIDE; METFORMIN HCL; ATORVASTATIN; BISOPROLOL; PERINDOPRIL ERBUMINE; OMEPRAZOLE	This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 06-Jan-2022 and was forwarded to Moderna on 06-Jan-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDIAL INFARCTION (Myocardial infarction) in a 54-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (batch no. 3004668) for an unknown indication. The patient's past medical history included Coronary angioplasty (Cardiac angioplasty to right coronary artery and LAD). Concurrent medical conditions included Type 2 diabetes mellitus and Hyperlipidaemia. Concomitant products included CLOPIDOGREL from 02-May-2021 to an unknown date, ACETYLSALICYLIC ACID (ASPIRIN (E.C.)) from 02-May-2021 to an unknown date, ISOSORBIDE MONONITRATE from 02-May-2021 to an unknown date, ACARBOSE from 02-May-2021 to an unknown date, GLICLAZIDE from 02-May-2021 to an unknown date, METFORMIN HCL from 02-May-2021 to an unknown date, ATORVASTATIN from 02-May-2021 to an unknown date, BISOPROLOL from 02-May-2021 to an unknown date, PERINDOPRIL ERBUMINE from 02-May-2021 to an unknown date and OMEPRAZOLE from 02-May-2021 to an unknown date for an unknown indication. On 27-Jul-2021 at 9:56 AM, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (Intramuscular) 1 dosage form. On 04-Aug-2021 at 7:50 AM, the patient experienced MYOCARDIAL INFARCTION (Myocardial infarction) (seriousness criteria death and medically significant). An autopsy was not performed. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (Intramuscular), the reporter did not provide any causality assessments.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							No treatment medications were reported. Company Comment: This case refers to a 54-year-old male patient with a medical history of coronary angioplasty who experienced the unexpected event of Myocardial infarction approximately 8 days after the first dose of mRNA-1273 vaccine. No causality assessment was provided by the reporter. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events seriousness assessed as per Regulatory Authority reporting.	
[redacted]	BRUNEI DARUSSALAM	Cardiac failure	43.00	Female	Haemorrhagic transformation stroke(H); Infarction(H); Cholecystectomy; Endocarditis(H)	FUROSEMIDE; AMLODIPINE; SACUBITRIL;VALSARTAN; GABAPENTIN; LORATADINE; ALPRAZOLAM; BISOPROLOL; GLICLAZIDE; LINAGLIPTIN; SPIRONOLACTONE; DABIGATRAN	This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 06-Jan-2022 and was forwarded to Moderna on 06-Jan-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of CARDIAC FAILURE (Decompensated heart failure secondary to non compliance to medication) in a 43-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (batch no. 3004736) for an unknown indication. The patient's past medical history included Haemorrhagic transformation due to acute stroke (Haemorrhagic transformation of sub acute infarct.) in May 2021, Infarction (old infarct seen in right occipital and right cerebellum. seizure activity), Endocarditis (Infective endocarditis MSSA with spondylodiscitis) in May 2021 and Cholecystectomy (Lap cholecystectomy) in 2013. Concomitant products included FUROSEMIDE from 06-Oct-2021 to an unknown date, AMLODIPINE from 06-Oct-2021 to an unknown date, SACUBITRIL;VALSARTAN from 06-Oct-2021 to an unknown date, GABAPENTIN from 06-Oct-2021 to an unknown date, LORATADINE from 06-Oct-2021 to an unknown date, ALPRAZOLAM from 06-Oct-2021 to an unknown date, BISOPROLOL from 06-Oct-2021 to an unknown date, GLICLAZIDE from 06-Oct-2021 to an unknown date, LINAGLIPTIN from 06-Oct-2021 to an unknown date, SPIRONOLACTONE from 06-Oct-2021 to an unknown date and DABIGATRAN from 06-Oct-2021 to an unknown date for an unknown indication. On 12-Oct-2021 at 11:22 AM, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (Intramuscular) 1 dosage form. On 13-Oct-2021, the patient experienced CARDIAC FAILURE (Decompensated heart failure secondary to non compliance to medication) (seriousness criteria death and medically significant). The reported cause of death was decompensated heart failure secondary to non compliance to medication. An autopsy was performed, but no results were provided.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							For mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (Intramuscular), the reporter did not provide any causality assessments. No treatment drug information provided. Patient also took Aqueous cream 1 app BD and Methyl salicylate, Menthol + Eugenol 1 app TDS as concomitant drug. Company Comment: This case refers to a 43-year-old female patient with a medical history of endocarditis who experienced the unexpected event of Cardiac failure approximately 1 day after the first dose of mRNA-1273 vaccine. No causality assessment was provided by the reporter. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting.	
[redacted]	FRANCE	Death	98.00	Female	Asthma(H); Hypertension(C); Dementia Alzheimer's type(C); Hypercholesterolaemia(H); Type 2 diabetes mellitus(C)	0	This case was received via European Medicines Agency (Reference number: [redacted] on 07-Jan-2022 and was forwarded to Moderna on 07-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of DEATH (Unknown) in a 98-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 018G21A) for COVID-19 vaccination. The patient's past medical history included Asthma and Hypercholesterolemia. Concurrent medical conditions included Hypertension arterial, Dementia of the Alzheimer's type NOS and Type 2 diabetes mellitus. On 16-Dec-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. Death occurred on an unknown date It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were provided. No treatment medications were provided. Company Comment: This case concerns a 98-year-old, female patient with reported relevant medical history of Asthma, Hypertension arterial, Dementia of the Alzheimer's type NOS, Hypercholesterolemia and Type 2 diabetes mellitus, who experienced the fatal serious unexpected event of Death, cause of death not provided, Autopsy was also not done. Death was reported to occur in an unknown date after the administration of the second dose of the mRNA-1273 vaccine. Event seriousness assessed as per Regulatory Authority as Death; limited information was provided at this time. he benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	[redacted]
[redacted]	FRANCE	Vaccination failure	74.00	Male	Rheumatoid arthritis(H); Hypertension(H);	TRESIBA; METFORMINE [METFORMIN];	This case was received via European Medicines Agency (Reference number: [redacted] on 10-Jan-2022 and was forwarded to Moderna on 10-Jan-2022.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
					Diabetes mellitus(H); Transient ischaemic attack(H)	AMLODIPINE; KARDEGIC; METHOTREXATE; PERINDOPRIL; ALLOPURINOL; BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE; REPAGLINIDE; ACIDE FOLIQUE	This regulatory authority case was reported by a physician and describes the occurrence of VACCINATION FAILURE (Unknown) in a 74-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Arthritis rheumatoid, Hypertension arterial, Diabetes and TIA. Concomitant products included INSULIN DEGLUDEC (TRESIBA), METFORMIN (METFORMINE [METFORMIN]), AMLODIPINE, ACETYLSALICYLATE LYSINE (KARDEGIC), METHOTREXATE, PERINDOPRIL, ALLOPURINOL, BISOPROLOL FUMARATE, HYDROCHLOROTHIAZIDE, REPAGLINIDE and FOLIC ACID (ACIDE FOLIQUE) for an unknown indication. In June 2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) I dosage form. On 01-Nov-2021, the patient experienced VACCINATION FAILURE (Unknown) (seriousness criterion death). The patient died on 23-Nov-2021. The reported cause of death was acute respiratory distress syndrome - covid. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 05-Nov-2021, SARS-CoV-2 test: positive (Positive) Positive. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Treatment information was not provided by the reporter. Most recent FOLLOW-UP information incorporated above includes: On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 07-Jan-2022.	
[redacted]	AUSTRIA	Death	73.00	Male	Diabetes mellitus(C); Hypertension(C); COVID-19 VACCINE MODERNA(H); COVID-19 VACCINE MODERNA(H)	0	This case was received via European Medicines Agency (Reference number:[redacted] on 10-Jan-2022 and was forwarded to Moderna on 10-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (Death) in a 73-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Previously administered products included for Product used for unknown indication: COVID-19 VACCINE MODERNA and COVID-19 VACCINE MODERNA. Past adverse reactions to the above products included No adverse event with COVID-19 VACCINE MODERNA and COVID-19 VACCINE MODERNA.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							Concurrent medical conditions included Diabetes mellitus and Hypertension arterial. On 01-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. Death occurred on 23-Dec-2021 It is unknown if an autopsy was performed. Concomitant product use was not provided by the reporter. No treatment information was provided. Company Comment: This is a regulatory case concerning a 73-year-old, male patient with medical history of diabetes mellitus and hypertension, who experienced the unexpected serious event Death. The event occurred approximately 22 days after the third dose of mRNA-1273 vaccine. Cause of death was not reported. It is unknown if an autopsy was performed. The medical history reported and patient's age remain as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. case was assessed as serious as per Regulatory Authority's report due to death.	
[redacted]	UNITED STATES	Acute respiratory distress syndrome, COVID-19 pneumonia, Vaccine induced antibody absent	70.00	Male	End stage renal disease(H); Left ventricular failure(C); Type 1 diabetes mellitus(C); Renal transplant	MYCOPHENOLATE; TACROLIMUS; PREDNISONE	This literature-non-study case was reported in a literature article and describes the occurrence of ACUTE RESPIRATORY DISTRESS SYNDROME (Acute respiratory distress syndrome) and COVID-19 PNEUMONIA (COVID-19 pneumonia) in a 70-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. LITERATURE REFERENCE: Adedoyin O, Brijmohan S,Lavine R, Lisung FG. Undetectable SARS-CoV-2 active adaptive immunity post-vaccination or post-COVID-19 severe disease after immunosuppressants use. BMJ Case Rep. 2021;14:e246308 The patient's past medical history included End stage renal failure (renal transplant 6 months ago) and Renal transplant (6 months ago). Concurrent medical conditions included Diastolic heart failure and Insulin-dependent diabetes mellitus. Concomitant products included MYCOPHENOLATE MOFETIL (MYCOPHENOLATE), TACROLIMUS and PREDNISONE for Renal transplant. On 14-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 14-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient experienced ACUTE RESPIRATORY DISTRESS SYNDROME (Acute respiratory distress syndrome) (seriousness criteria death,	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							hospitalization and medically significant), COVID-19 PNEUMONIA (COVID-19 pneumonia) (seriousness criteria death and medically significant) and VACCINE INDUCED ANTIBODY ABSENT (Vaccine induced antibody absent). The patient was treated with CONVALESCENT PLASMA COVID-19 for ARDS and COVID-19 pneumonia, at an unspecified dose and frequency; REMDESIVIR for ARDS and COVID-19 pneumonia, at an unspecified dose and frequency; DEXAMETHASONE for ARDS and COVID-19 pneumonia, at an unspecified dose and frequency; BAMLANIVIMAB on 20-Mar-2021 for COVID-19 pneumonia and ARDS, at an unspecified dose and frequency; APIXABAN for ARDS and COVID-19 pneumonia, at an unspecified dose and frequency and ETESEVIMAB for COVID-19 pneumonia and ARDS, at an unspecified dose and frequency. The patient died on an unknown date. The reported cause of death was ards and COVID-19 pneumonia. It is unknown if an autopsy was performed. At the time of death, VACCINE INDUCED ANTIBODY ABSENT (Vaccine induced antibody absent) outcome was unknown. Related DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2020, Chest X-ray: abnormal Chest X-ray showing diffuse bilateral mixed interstitial/ alveolar opacities.. In 2020, SARS-CoV-2 antibody test: negative (Negative) Negative. On 19-Mar-2021, SARS-CoV-2 RNA: positive (Positive) Positive. On 31-Mar-2021, SARS-CoV-2 antibody test: negative (Negative) Negative. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter considered ACUTE RESPIRATORY DISTRESS SYNDROME (Acute respiratory distress syndrome), COVID-19 PNEUMONIA (COVID-19 pneumonia) and VACCINE INDUCED ANTIBODY ABSENT (Vaccine induced antibody absent) to be related. Patient Treatment also includes broad-spectrum antibiotics. Company comment: This literature-non-study case concerns a 70-year-old male patient with relevant medical history of end stage renal disease leading to renal transplant 6 months prior to this report, diabetes mellitus and diastolic heart failure and concurrent use of prednisone, tacrolimus and mycophenolate, who experienced serious unexpected fatal AESI events of acute respiratory distress syndrome and COVID-19 pneumonia and non-serious unexpected event of vaccine induced antibody absent. The events occurred approximately a month after the 2nd dose of the mRNA-1273. The rechallenge was not applicable due to occurrence after the 2nd dose. Patient's concomitant medications used for renal transplant rejection prevention are possible confounders for the	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							events. The event of ARDS was secondary to COVID-19. Based on the current available information, the mRNA-1273 does not contain a virus capable of causing COVID-19 infection after vaccination. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 13-Jan-2022: Follow up received by safety 13-Jan-2022 included an Email with FTA received from SARA team and contain significant information. Lab Data, Treatment drugs, event outcome were added.	
[redacted]	THAILAND	Dyspnoea, Mouth haemorrhage	85.00	Male	Embolic stroke(H); Atrial fibrillation(H)	0	This case was received via Zuellig Pharma (Reference number: [redacted] on 10-Jan-2022 and was forwarded to Moderna on 11-Jan-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of MOUTH HAEMORRHAGE (He had red blood out of his mouth) and DYSPNOEA (He had fast breathing) in an 85-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 3005841) for an unknown indication. The patient's past medical history included Embolic stroke (Embolic stroke+AF) and Atrial fibrillation (Embolic stroke+AF). On 02-Dec-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On 09-Dec-2021 at 10:00 PM, the patient experienced MOUTH HAEMORRHAGE (He had red blood out of his mouth) (seriousness criterion death) and DYSPNOEA (He had fast breathing) (seriousness criterion death). The patient died on 09-Dec-2021. The reported cause of death was he had red blood out of his mouth and he had fast breathing. It is unknown if an autopsy was performed. For mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown), the reporter considered MOUTH HAEMORRHAGE (He had red blood out of his mouth) and DYSPNOEA (He had fast breathing) to be not related. No concomitant medication information was provided. No treatment medication was provided. After vaccination, he had no fever, no abnormal symptom, could eat and no choking. On 09-Dec-2021, he could eat properly and no choking in the morning and in the afternoon. In the evening, he did not eat and slept. At 10:00 pm, he had fast breathing and before he passed away he had red blood out of his mouth. He passed away at 10:30 pm at home.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							Company comment: This case concerns an 85-year-old male patient with relevant medical history of Embolic Stroke and Atrial fibrillation, who experienced the unexpected serious events of Mouth Hemorrhage and Dyspnea, the events led to the death of the patient as reported by the regulatory authority. The events occurred in 7 days and 22 hours after receiving the first dose of mRNA-1273 Vaccine. The reported cause of death was he had red blood out of his mouth, and he had fast breathing. It is unknown if an autopsy was performed. No clinical or treatment details were given. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.	
[redacted]	THAILAND	Acute kidney injury, Back pain, Dyspnoea, Fatigue, Myocardial infarction, Vomiting	61.00	Male	Diabetes mellitus(C)	0	This case was received via Zuellig Pharma (Reference number: [redacted] on 10-Jan-2022 and was forwarded to Moderna on 11-Jan-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of DYSPNOEA (Severe dyspnea), ACUTE KIDNEY INJURY (Acute renal failure), MYOCARDIAL INFARCTION (Acute myocardial infraction), VOMITING (vomiting), FATIGUE (tiredness) and BACK PAIN (Back pain) in a 61-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 049F21A) for an unknown indication. Concurrent medical conditions included Diabetes. On 08-Dec-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On 14-Dec-2021, the patient experienced DYSPNOEA (Severe dyspnea) (seriousness criteria death and medically significant), ACUTE KIDNEY INJURY (Acute renal failure) (seriousness criteria death and medically significant), MYOCARDIAL INFARCTION (Acute myocardial infraction) (seriousness criteria death and medically significant) and VOMITING (vomiting) (seriousness criterion death). On 15-Dec-2021, the patient experienced FATIGUE (tiredness) (seriousness criterion death) and BACK PAIN (Back pain) (seriousness criterion death). The patient died on 16-Dec-2021. The reported cause of death was Vomiting, Tiredness, Back pain, acute myocardial infraction, Acute renal failure and severe dyspnea. It is unknown if an autopsy was performed. The action taken with mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown) was unknown. For mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown), the reporter did not provide any causality assessments. Concomitant medication information was not provided by the reporter. Treatment information was not provided by the reporter.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							Patient's race was reported as Thai. On 16-Dec-2021, the vaccine recipient's relative brought him to the hospital. He was very tired and put on endotracheal tube, CPR and death. It was reported that the date of treatment was on 16-Dec-2021. Serial no: [redacted] Company comment: This is a regulatory case concerning a 61-year-old, male patient with a history of Diabetes, who experienced the serious (fatal) unexpected , according CCDS, AESI of Acute kidney injury and Myocardial infarction and the serious (fatal) events of Dyapnoea, Vomiting, Fatigue and Back pain . The events dyspnoea, vomiting, fatigue and back pain could be in association to the acute kidney injury. The events Dyspnoea, vomiting, acute kidney injury and myocardial infarction occurred approximately 6 days after the first dose of mRNA-1273 vaccine. The events fatigue and back pain occurred approximately 7 days after the first dose of mRNA-1273 vaccine. The rechallenge was not applicable due to the fatal outcome. The patient died on 16-Dec-2021, 8 days after the first dose of mRNA-1273 vaccine. The medical history of Diabetes mellitus remains as a confounder as poorly controlled diabetes can cause acute kidney injury contributing to the fatal outcome and may be a risk factor to develop heart disease. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	
[redacted]	KOREA, REPUBLIC OF	Decreased appetite, Interchange of vaccine products, Loss of consciousness, Salivary hypersecretion, Sudden death	35.00	Male	Intellectual disability(C); ASTRAZENECA COVID-19 VACCINE; ASTRAZENECA COVID-19 VACCINE	0	This spontaneous case was reported by a consumer and describes the occurrence of SUDDEN DEATH (Sudden death/died shortly thereafter), LOSS OF CONSCIOUSNESS (patient collapsed) and SALIVARY HYPERSECRETION (salivated) in a 35-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. The occurrence of additional non-serious events is detailed below. Previously administered products included for COVID-19 vaccination: ASTRAZENECA COVID-19 VACCINE (first dose) on 13-Apr-2021 and ASTRAZENECA COVID-19 VACCINE (second dose) on 29-Jun-2021. Past adverse reactions to the above products included No adverse event with ASTRAZENECA COVID-19 VACCINE and ASTRAZENECA COVID-19 VACCINE. Concurrent medical conditions included Intellectual disability (congenital intellectual disability with mental age of two to three years.). On 10-Dec-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 10-Dec-2021, the patient experienced INTERCHANGE OF VACCINE PRODUCTS (Previously had received two doses of AstraZeneca COVID-19 vaccine). In December 2021, the patient experienced DECREASED APPETITE (did not eat well). On 30-Dec-2021 at 2:50 AM, the patient experienced LOSS OF CONSCIOUSNESS (patient collapsed) (seriousness criteria death and medically significant) and SALIVARY HYPERSECRETION	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							(salivated) (seriousness criterion death). On 10-Dec-2021, INTERCHANGE OF VACCINE PRODUCTS (Previously had received two doses of AstraZeneca COVID-19 vaccine) had resolved. The patient died on 30-Dec-2021. An autopsy was performed. The autopsy did not show any specific finding, therefore an additional autopsy was requested. At the time of death, DECREASED APPETITE (did not eat well) outcome was unknown. The patient had congenital intellectual disability, where the mental age was two to three years. It was reported that he was healthy without any other underlying diseases or medical histories. After the booster dose, the patient did not eat well. At 2:50 AM of 30-DEC-2021, on the way to the toilet, the patient collapsed and salivated and died shortly thereafter. The autopsy performed initially did not show any specific finding. An additional autopsy was requested for further investigation. Company comment: This is a ace of Interchange of vaccine products for this 35-year-old male patient with no relevant medical history. Reportedly, the patient had received two doses of AstraZeneca COVID-19 vaccine and after these doses, the patient had received the mRNA-1273 vaccine (company product) as third dose (booster). Therefore, Interchange of vaccine products is considered in this specific case. The patient developed non serious unexpected event of Decreased appetite, as well as serious unexpected events of Sudden death, Salivary hypersecretion and Loss of consciousness after receiving the mRNA-1273 vaccine, as third dose (booster). The event of Decreased appetite occurred on an unknown date, shortly after vaccination, however, the exact start date was not specified. Twenty days after the vaccination, on the way to the toilet, the patient collapsed and salivated and died shortly thereafter. The autopsy was performed and since it did not show any specific finding, an additional autopsy was requested for further investigation. At the time of this report, it remained unknown if this additional requested autopsy was actually performed. Therefore, the exact cause of death remained unknown at this moment. Limited information precludes a meaningful medical assessment. The rechallenge is not applicable since the patient died. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.	
[redacted]	THAILAND	Cardiac arrest	72.00	Male	Myocardial ischaemia(C)	0	This case was received via Zuellig Pharma (Reference number: [redacted]) on 10-Jan-2022 and was forwarded to Moderna on 11-Jan-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of CARDIAC ARREST (Sudden Cardiac arrest) in a 72-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. TRC3005841) for an unknown indication. Concurrent medical conditions included Chronic ischaemic heart disease, unspecified (I259 Chronic ischaemic heart disease - Chronic ischaemic heart disease,	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							unspecified). On 03-Dec-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On 15-Dec-2021, the patient experienced CARDIAC ARREST (Sudden Cardiac arrest) (seriousness criterion death). It is unknown if an autopsy was performed. The action taken with mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown) was unknown. For mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown), the reporter did not provide any causality assessments. No concomitant medication was reported. Patient took unspecified treatment on 15-DEC-2021. The suspect product serial n was mentioned as TRC3005841. Company Comment - This regulatory authority case concerns a 72 year old male patient with medical history of chronic ischaemic heart disease, who experienced the serious unexpected events of cardiac arrest. The event occurred 12 days after the first dose of mRNA-1273 vaccine. Date and cause of death were undisclosed. Patient's medical history of chronic ischaemic heart disease remains a confounder. The rechallenge was not applicable. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.	
[redacted]	THAILAND	COVID-19 pneumonia, Respiratory failure	91.00	Female	Hypertension(C); Dyslipidaemia(C); Insomnia(H); Coronary artery disease(H)	0	This case was received via Zuellig Pharma (Reference number: [redacted] on 10-Jan-2022 and was forwarded to Moderna on 11-Jan-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of COVID-19 PNEUMONIA (Pyrexia, cough, rhinorrhea, secretion discharge, fatigue and asthenia) and RESPIRATORY FAILURE (Covid pneumonia with respiratory failure) in a 91-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. TRC3005841) for an unknown indication. The patient's past medical history included Insomnia (Insomnia) and Coronary artery disease (CAD). Concurrent medical conditions included Hypertension (HT) and Dyslipidemia (DLP). On 03-Dec-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On 04-Dec-2021, the patient experienced COVID-19 PNEUMONIA (Pyrexia, cough, rhinorrhea, secretion discharge, fatigue and asthenia) (seriousness criteria death and medically significant) and RESPIRATORY FAILURE (Covid pneumonia with respiratory failure) (seriousness criteria death and medically significant). The reported cause of death was covid pneumonia, Respiratory failure, high fever, cough with mucus, mild runny	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							nose, mucus in her throat, fatigue/tiredness, Weakness and covid-19. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 09-Dec-2021, SARS-CoV-2 test: positive (Positive) Positive. For mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown), the reporter did not provide any causality assessments. Concomitant medication information was not provided by the reporter. Date of treatment was 09-DEC-2021. The Patient experienced after vaccination on 04-DEC-2021 high fever, cough with mucus, mild runny nose, on 07-DEC-2021 eat slowly, on 08-DEC-2021 could not drink the water and her relative provided the water to her through the spoon, mucus in her throat, fatigue, on 09-DEC-2021 tiredness, weakness then her relative called the hospital. Lab data included COVID-19 test, Rapit test, performed at emergency room on 12-DEC-2021 08:20 am and result of Rapit test was positive and ordered RT-PCR. The result was detected on 09-DEC-2021. The vaccine recipient's relative provided paracetamol, expectorant drug to her and her symptoms were improved. Company Comment : This is a regulatory authority case concerning a 91-year-old, female patient with relevant medical history of hypertension and coronary artery disease, who experienced the unexpected serious events of Covid-19 pneumonia and respiratory failure. The events Covid-19 pneumonia and respiratory failure exact occurrence unknown but stated that the events occurred after the first dose of mRNA-1273 vaccine administration. The events were described as, 1 day after the first dose of mRNA-1273 vaccine the patient experienced high fever, cough with mucus and mild runny nose. The patient was given paracetamol and expectorant by her relative and allegedly her symptoms improved. 4 days after the first dose of mRNA-1273 vaccine administration patient was able to eat slowly from the usual 15 minutes to 30 minutes. 5 days after the first dose of mRNA-1273 vaccine administration patient could not drink water and her relative provided the water to her through the spoon and with mucus in her throat and fatigue. 6 days after the first dose of mRNA-1273 vaccine administration patient's fatigue continued accompanied by weakness and was brought to ER and the patient was tested positive on Covid-19 rapid test. The outcome of the events Covid-19 pneumonia and respiratory failure was fatal. The patient's age and medical history of hypertension and coronary artery disease remain confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
[redacted]	THAILAND	Acute kidney injury, Asthenia, Dizziness, Dyspnoea, Dyspnoea exertional, Fatigue, Feeding disorder, Hot flush, Hypoglycaemia, Nausea, Vertigo, Vomiting	55.00	Male	Diabetes mellitus(C)	0	This case was received via Zuellig Pharma (Reference number: [redacted] on 10-Jan-2022 and was forwarded to Moderna on 11-Jan-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of ACUTE KIDNEY INJURY (Acute renal failure), DIZZINESS (Dizziness/ increased dizziness), NAUSEA (nausea), VERTIGO (Vertigo), VOMITING (Vomiting 2-3 times/day), FEEDING DISORDER (Unable to eat), FATIGUE (Fatigue), HOT FLUSH (Hot flashes sometimes), DIZZINESS (dizziness), ASTHENIA (felt weakness), DYSPNOEA (Shortness of breath/Dypnea), FATIGUE (Get tired easily), DYSPNOEA EXERTIONAL (Intermittent episodes of exertion) and HYPOGLYCAEMIA (At night, had hypoglycemia sometimes) in a 55-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 021F21A) for an unknown indication. Concurrent medical conditions included Diabetes mellitus. On 27-Nov-2021, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On 28-Nov-2021, the patient experienced DYSPNOEA (Shortness of breath/Dypnea) (seriousness criterion medically significant), FATIGUE (Get tired easily) (seriousness criterion medically significant) and DYSPNOEA EXERTIONAL (Intermittent episodes of exertion) (seriousness criterion medically significant). On 08-Dec-2021, the patient experienced HOT FLUSH (Hot flashes sometimes) (seriousness criterion medically significant), DIZZINESS (dizziness) (seriousness criterion medically significant), ASTHENIA (felt weakness) (seriousness criterion medically significant) and HYPOGLYCAEMIA (At night, had hypoglycemia sometimes) (seriousness criterion medically significant). On 15-Dec-2021, the patient experienced DIZZINESS (Dizziness/ increased dizziness) (seriousness criteria hospitalization and medically significant), NAUSEA (nausea) (seriousness criteria hospitalization and medically significant), VERTIGO (Vertigo) (seriousness criteria hospitalization and medically significant), VOMITING (Vomiting 2-3 times/day) (seriousness criteria hospitalization and medically significant), FEEDING DISORDER (Unable to eat) (seriousness criteria hospitalization and medically significant) and FATIGUE (Fatigue) (seriousness criteria hospitalization and medically significant). On 16-Dec-2021, the patient experienced ACUTE KIDNEY INJURY (Acute renal failure) (seriousness criteria death, hospitalization and medically significant). The patient was hospitalized on sometime in December 2021 due to ACUTE KIDNEY INJURY, DIZZINESS, FATIGUE, FEEDING DISORDER, NAUSEA, VERTIGO and VOMITING. The patient died on 23-Dec-2021. The reported cause of death was Acute renal failure. It is unknown if an autopsy was performed. At the time of death, DIZZINESS (Dizziness/ increased dizziness), NAUSEA (nausea), VERTIGO (Vertigo), VOMITING (Vomiting 2-3 times/day), FEEDING DISORDER (Unable to eat), FATIGUE (Fatigue), HOT FLUSH (Hot flashes sometimes),	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							DIZZINESS (dizziness), ASTHENIA (felt weakness), DYSPNOEA (Shortness of breath/Dypnea), FATIGUE (Get tired easily) and DYSPNOEA EXERTIONAL (Intermittent episodes of exertion) outcome was unknown and HYPOGLYCAEMIA (At night, had hypoglycemia sometimes) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 08-Dec-2021, Blood glucose: 120-157 (abnormal) pre meal: 120-157 mg %, 45 (abnormal) 45 mg%, 55 (abnormal) 55 mg% and 67 (abnormal) 67 mg%. On 08-Dec-2021, Chest X-ray: no infiltration (normal) no infiltration. For mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown), the reporter did not provide any causality assessments. Patient's relevant medical history information included B24. No concomitant medications were reported. On 28-Nov-2021, patient had normal urination and legs were not swollen. Patient took sweet water for hypoglycemia and had got better. On 15-Dec-2021, patient had no chest tightness, no arm and leg weakness, no fever and no palpitations. Patient took unknown medications at home. This is a regulatory case concerning a 55-year-old, male patient with a history of Diabetes mellitus, who experienced the serious (Fatal) unexpected , according CCDS, AESI of Acute kidney injury and the serious unexpected, according CCDS, events of Dizziness (reported as Dizziness & Dizziness/ increased dizziness), Nausea, Vertigo, Vomiting, Feeding disorder, Fatigue (reported as Fatigue & Get tired easily), Hot flush, Asthenia, Dyspnoea, Dyspnoea exertional and Hypoglycemia . The events Dyspnoea, Dyspnoea exertional and fatigue (reported as get tired easily) occurred approximately one day after the second dose of mRNA-1273 vaccine. The events hot flush, dizziness (reported as dizziness), asthenia and hypoglycaemia occurred approximately 11 days after the second dose of mRNA-1273 vaccine. The events dizziness (reported as dizziness aggravated), nausea, vertigo, vomiting, feeding disorder and fatigue (reported as fatigue) occurred approximately 18 days after the second dose of mRNA-1273 vaccine. The even Acute kidney injury occurred approximately 19 days after the second dose of mRNA-1273 vaccine and had fatal outcome, with death occurring 26 days after the second dose of mRNA-1273 vaccine. The rechallenge was not applicable since the events occurred after the second dose of vaccine and patient died. It is unknown if an autopsy was performed. The medical history of Diabetes mellitus remains as a confounder as poorly controlled diabetes can cause acute kidney injury contributing to the fatal outcome. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	
[redacted]	GERMANY	Sudden cardiac death	64.00	Male	Arteriosclerosis coronary artery(H);	0	This case was initially received via European Medicines Agency (Reference number: [redacted] on 12-Jan-2022.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
					Myocardial infarction(H); Coronary artery insufficiency(H)		The most recent information was received on 28-Mar-2022 and was forwarded to Moderna on 28-Mar-2022. This regulatory authority case was reported by a physician and describes the occurrence of SUDDEN CARDIAC DEATH (Sudden cardiac death) in a 64-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Date of death not specified. The patient's past medical history included Coronary sclerosis, Old myocardial infarction and Coronary insufficiency. On 15-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. The patient died on 21-Dec-2021. The reported cause of death was 10049418. An autopsy was performed. The autopsy-determined cause of death was as a result of coronary sclerosis. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. Treatment information was not provided. Company comment: This is a regulatory authority case concerning a 64-year-old, male patient with relevant medical history of coronary sclerosis, old myocardial infarction and coronary insufficiency who experienced the unexpected serious AESI event of sudden cardiac death. The event occurred approximately 6 days after the unknown dose number of mRNA-1273 vaccine administration. The reported cause of death was sudden cardiac death, and the autopsy-determined cause of death was as a result of coronary sclerosis. No other information surrounding the event was reported. The medical history of coronary sclerosis, old myocardial infarction and coronary insufficiency remain confounders for the event sudden cardiac death. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 28-Mar-2022: Significant follow-up contains updated patient demographics, patient history, patient death date, autopsy result, and deletion of event myocarditis. On 29-Mar-2022: Non significant follow-up received includes contains no new information.	
[redacted]	FRANCE	Death	85.00	Male	Cardiac failure(C); Diabetes mellitus(C); Hypertension(C); Arrhythmia(H);	COMIRNATY	This case was received via European Medicines Agency (Reference number: [redacted] on 15-Jan-2022 and was forwarded to Moderna on 15-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of DEATH (fatalities) in an 85-year-old	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
					Hypoacusis(H); Silicosis(H); Hepatic mass(H); Ventricular dysfunction(C); Inguinal hernia(H)		male patient who received mRNA-1273 (Spikevax) (batch no. 3005242) for COVID-19 vaccination. The patient's past medical history included Cardiac arrhythmia, Hypoacusis, Silicosis, Hepatic mass and Hernia inguinal. Concurrent medical conditions included Decompensation cardiac, Diabetes, Hypertension arterial and Ventricular dysfunction. Concomitant products included TOZINAMERAN (COMIRNATY) for COVID-19 vaccination. On 15-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. Death occurred on 15-Dec-2021 The patient died on 15-Dec-2021. It is unknown if an autopsy was performed. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Treatment details were not provided. Company Comment: This is a regulatory case concerning an 85-year-old, male patient with medical history including Ventricular dysfunction, Cardiac arrhythmia, Decompensation cardiac, Diabetes, Hypertension arterial, Silicosis and Hepatic mass, with an Interchange of vaccine products (TOZINAMERAN (COMIRNATY) for COVID-19 vaccination), who experienced the unexpected serious event of death. The event occurred approximately on the same day after a dose of mRNA-1273 vaccine. It is unknown if an autopsy was performed. No cause of death was reported. The medical history and patient's age remain as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 14-Jan-2022.	
[redacted]	UNITED KINGDOM	Circulatory collapse, Cough, Delirium, Empyema, Pyrexia	83.00	Male	Diabetes mellitus(C); Chronic obstructive pulmonary disease(C); Suspected COVID-19(C)	0	This case was received via United Kingdom MHRA (Reference number: [redacted] on 14-Jan-2022 and was forwarded to Moderna on 14-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of EMPYEMA (Empyema), DELIRIUM (Delirium), CIRCULATORY COLLAPSE (Circulatory collapse), COUGH (Coughing) and PYREXIA (Fever) in an 83-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for an unknown indication.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							Concurrent medical conditions included Diabetic (type 2 diabetic well managed), COPD (well managed) and Suspected COVID-19 (Unsure when symptoms started). In November 2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. In 2021, the patient experienced COUGH (Coughing) (seriousness criteria death and hospitalization) and PYREXIA (Fever) (seriousness criteria death and hospitalization). On 09-Dec-2021, the patient experienced EMPYEMA (Empyema) (seriousness criteria death and hospitalization). On an unknown date, the patient experienced DELIRIUM (Delirium) (seriousness criteria death and hospitalization). an unknown date, the patient experienced CIRCULATORY COLLAPSE (Circulatory collapse) (seriousness criteria death and hospitalization). The patient died on 28-Dec-2021. The reported cause of death was Empyema and Delirium. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, SARS-CoV-2 test: negative (Negative) Negative COVID-19 test. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. No concomitant medications were provided. No treatment medications were provided. It was reported that, approximately 7 days after the booster vaccine, patient felt very unwell, coughing and fever. About 5 days later he collapsed at home and was taken into hospital. He did not have COVID-19. About 3 days after being admitted into hospital, it was confirmed that he had an empyema. This worsened, causing delirium and he was unable to have a chest drain. He died in hospital about 5 weeks after he had his booster jab. He did not tested positive for COVID-19 after taking the vaccine. He was not enrolled in clinical trial. It was reported that, his reaction was not related to possible inflammation of the heart (myocarditis or pericarditis). Company comment: This case concerns a 83-year-old male patient with medical history of diabetes type 2, COPD and suspected COVID-19, who experienced the serious (fatal and hospitalization) unexpected events of empyema, delirium, circulatory collapse, pyrexia and cough after the third dose of mRNA-1273. It was reported that approximately 7 days after the booster vaccine, the patient felt very unwell, coughing and fever. About 5 days later he collapsed at home and was taken into hospital. It was reported that he did not have COVID. About 3 days after being admitted into hospital, it was confirmed that he had an empyema. This worsened,	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							causing delirium and he was unable to have a chest drain. The patient died on 28-DEC-2021, cause of death was reported as empyema and delirium. Unknown if an autopsy was performed. Patient´s underlying diabetes remains a contributing factor for the event empyema. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	
[redacted]	ITALY	Pyrexia, Tremor, Vomiting	90.00	Male	Osteoarthritis(H); Arrhythmia(H)	0	This case was initially received via European Medicines Agency (Reference number: [redacted] on 14-Jan-2022. The most recent information was received on 29-Jan-2022 and was forwarded to Moderna on 29-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of PYREXIA (Vomiting, Tremor, Fever), TREMOR (Vomiting, Tremor, Fever) and VOMITING (Vomiting, Tremor, Fever) in a 90-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Arthrosis and Arrhythmia (Heart arrhythmias.). On 24-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 24-Dec-2021, the patient experienced PYREXIA (Vomiting, Tremor, Fever) (seriousness criterion death), TREMOR (Vomiting, Tremor, Fever) (seriousness criterion death) and VOMITING (Vomiting, Tremor, Fever) (seriousness criterion death). The patient died on 25-Dec-2021. It is unknown if an autopsy was performed. No concomitant medications were provided.Treatment medications were not provided. Patient received Pfizer as a first dose. Rep comments: Previous vaccinations: Pfizer as a first dose, Moderna as a second dose. Reason for recall: Other or not known. - Flu vaccination was carried out on 2021-11-17. - Concomitant conditions: Knee and hip arthrosis; cardiac arrhythmias - Allergies: Dermatitis - Reaction time: 17:00 - Submitted by VigicoVid19-Card [redacted] comments: 30/12/2021 CRFV: requests for follow-up information on clinical documentation. Pending. 30/12/2021 CRFV: the card is updated with the info provided by the signaller and attaches docs clinics. Company Comment: This case concerns a 90-year-old male patient, with reported medical history of Arrhythmia, who experienced the fatal unexpected adverse events of Pyrexia, Tremor and Vomiting. The events occurred the same day of the administration of one dose of the mRNA-1273 vaccine in an unknown schedule of vaccination. The events were assessed by the reporter with the seriousness criteria of Death. No further	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							information on clinical course, treatments performed, or autopsy report was disclosed. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Previous vaccinations: Pfizer as a first dose, Moderna as a second dose. Reason for recall: Other or not known. - Flu vaccination was carried out on 2021-11-17. - Concomitant conditions: Knee and hip arthrosis; cardiac arrhythmias - Allergies: Dermatitis - Reaction time: 17:00 - Submitted by VigicoVid19-Card Most recent FOLLOW-UP information incorporated above includes: On 29-Jan-2022: Follow-up received included medical history added, indication updated	
[redacted]	UNITED STATES	Brain oedema, Dizziness, Pain in extremity, Pulmonary oedema, Seizure	37.00	Male	Glucose transporter type 1 deficiency syndrome(C); Dystonia(C); Metabolic encephalopathy(C); Migraine(C); Epilepsy(C); Gastrooesophageal reflux disease(C); Dysphagia(C); Cerebral palsy(C); Developmental delay(C); Hemiparesis(C); Joint contracture(C); Toe walking(C); Muscle spasticity(C); Hyperreflexia(C); Onychomycosis(C); Seasonal allergy; Temperature intolerance(C)	PROTONIX [OMEPRAZOLE]; PEPCID [FAMOTIDINE]; ALPHA LIPOIC ACID; DIAMOX [ACETAZOLAMIDE SODIUM]; ADVIL [IBUPROFEN]; ZYRTEC [CETIRIZINE HYDROCHLORIDE]; FLONASE [FLUTICASONE PROPIONATE]; CLARITIN ALLERGIC	This spontaneous case was reported by a physician and describes the occurrence of BRAIN OEDEMA (Cerebral edema), PULMONARY OEDEMA (Pulmonary edema) and SEIZURE (Probable seizures) in a 37-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TRIHEPTANOIN oral liquid for Glucose transporter type 1 deficiency syndrome. Concurrent medical conditions included Glucose transporter type 1 deficiency syndrome, Dystonia (Generalized dystonia), Metabolic encephalopathy, Migraine, Epilepsy (symptomatic generalized epilepsy), Gastroesophageal reflux disease, Dysphagia, Cerebral palsy, Developmental delay, Hemiparesis (right), Joint contracture (foot contracture), Toe walking, Muscle spasticity, Hyperreflexia, Onychomycosis, Seasonal allergy and Temperature intolerance. Concomitant products included FAMOTIDINE (PEPCID [FAMOTIDINE]) from 07-Aug-2020 to an unknown date for Dyspepsia, OMEPRAZOLE (PROTONIX [OMEPRAZOLE]) from 2020 to an unknown date for Eosinophilic oesophagitis, ACETAZOLAMIDE SODIUM (DIAMOX [ACETAZOLAMIDE SODIUM]) from 15-Jun-2015 to an unknown date for Epilepsy, ALPHA LIPOIC ACID from 2001 to an unknown date for Glucose transporter type 1 deficiency syndrome, IBUPROFEN (ADVIL [IBUPROFEN]) from 2012 to an unknown date for Headache, CETIRIZINE HYDROCHLORIDE (ZYRTEC [CETIRIZINE HYDROCHLORIDE]) from July 2019 to an unknown date, FLUTICASONE PROPIONATE (FLONASE [FLUTICASONE PROPIONATE]) from 13-Dec-2019 to an unknown date and OXYMETAZOLINE HYDROCHLORIDE (CLARITIN ALLERGIC) from July 2019 to an unknown date for Seasonal allergy. On 07-Aug-2020, the patient started TRIHEPTANOIN (Oral) 200 milligram once a day.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							On 19-Dec-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 19-Dec-2021, the patient experienced DIZZINESS (Unspecified Dizziness / Light headedness) and PAIN IN EXTREMITY (Sore arm). On 20-Dec-2021, the patient experienced BRAIN OEDEMA (Cerebral edema) (seriousness criteria death and medically significant), PULMONARY OEDEMA (Pulmonary edema) (seriousness criteria death and medically significant) and SEIZURE (Probable seizures) (seriousness criteria death and medically significant). The patient was treated with EPINEPHRINE (intravenous) at a dose of 2 doses, 2 milligram. The patient died on 20-Dec-2021. The reported cause of death was complications of glucose transporter type 1 deficiency syndrome. An autopsy was performed. The autopsy-determined cause of death was blood glucose level abnormal, moerate cerebral oedema, moderate pulmonary oedema, Splenomegaly, probable seizure that triggered an acute cardiac dysrhythmia leading to death, probable seizure that triggered an acute cardiac dysrhythmia leading to death, section of bilateral upper and lower lobe shows diffuse vascular congestion and focal accute neuronal necrsis or irreversible neuronal injury attributed to hypoxia-ischemia. At the time of death, DIZZINESS (Unspecified Dizziness / Light headedness) and PAIN IN EXTREMITY (Sore arm) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 26-Jun-2019, Anion gap (10-16): 5 (Low) 5 mmol/L. On 26-Jun-2019, Blood chloride (98-110): 116 (High) 116 mmol/L. On 26-Jun-2019, Blood urea (9-21): 8 (Low) 8 mg/dL. On 26-Jun-2019, Eosinophil count (25-600): 730 ul (High) 730 uL. On 26-Jun-2019, Full blood count: normal (normal) Normal. On 26-Jun-2019, Metabolic function test: normal (normal) normal. On 22-Dec-2021, Blood chloride (103-135): 121 (normal) 121 mmol/L. On 22-Dec-2021, Blood creatinine (0.6-135): 0.6 (normal) 0.6 mg/dL. On 22-Dec-2021, Blood glucose (Unknown-200): 35 (normal) 35 mg/dL (range less than 200). On 22-Dec-2021, Blood immunoglobulin E (5-79): 7 (normal) 7 IU / mL. On 22-Dec-2021, Blood potassium (Unknown-15): 9.67 (normal) 9.67 mmol/L. On 22-Dec-2021, Blood sodium (135-150): 137 (normal) 137 mmol/L. On 22-Dec-2021, Blood urea (8-20): 10 (normal) 10 mg/dL. On 22-Dec-2021, Tryptase (Unknown-11.4): 4 (normal) 4 ng/mL (range less than 11.4). On an unknown date, Blood glucose: 20 (abnormal) 20 and 25 (abnormal) 25. On an unknown date, Cytokine test: elevated cytokine (High) Elevated cytokine.	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Events onset from last dose to 1 day. Treatment medication mentioned epinephrine intravenous. Patient's mother stated that patient died in sleep during a nap at home. Patient's mother went to wake up before dinner and found unresponsive and after cardiopulmonary resuscitation (CPR) then called Emergency Medical Service who continued gave CPR for 35 minutes and administered 2 mg epinephrine intravenously. Reporter assessed event death as unlikely related to Triheptanoin. Reported initially that the autopsy was performed, and everything was normal, his organs were normal and there was nothing in his airways and no unusual findings were reported except the blood glucose level which were reported as 20 and 25. Reported that investigator assessed that event was unlikely related to Triheptanoin but possibly due to sudden cardiac arrest. Autopsy detailed mentioned later that the lung parenchyma was red-purple and moderately severely edematous, sections of the bilateral upper and lower lung showed diffused vascular congestion and congested alveoli, with extra vessels red blood cells. Spleen was enlarged weighing 340g with a smooth capsule. The brain was moderately edematous. Final neuropathological diagnosis was clinical history of glucose transporter type 1 deficiency syndrome identified as diffuse reactive astrocytes of the sub cortical white matter, deep nuclei and brain stem, and moderate cerebral oedema identified as bilateral uncal pressure grooves and acute hypoxic-ischemia changes in the cortex, hippocampus, and diencephalic nuclei. Autopsy results indicated that medical reporter reported it could have been seizure induced cardiac dysrhythmia leading to death. The medical examiner reported that elevated cytokines related to vaccine altered cerebral metabolism or produced central nervous system inflammation sufficient to lower threshold for seizure, but this was speculative as per them. Company comment: This spontaneous case concerns a 37-year-old male patient with relevant concurrent medical conditions of Glucose transporter type 1 deficiency syndrome, Dystonia (Generalized dystonia), Metabolic encephalopathy, Epilepsy (symptomatic generalized epilepsy), Cerebral palsy and Hyperreflexia, who experienced the unexpected serious fatal events of cerebral edema, pulmonary edema, and seizures, which occurred 1 day after the third dose (booster dose) of mRNA-1273 vaccine. Patient died 1 day after the vaccination during his sleep at home. The reported cause of death was complications of glucose transporter type 1 deficiency syndrome. The results from Autopsy reported as Blood glucose abnormal, Brain oedema, Pulmonary oedema, Splenomegaly, Seizure, Arrhythmia, Pulmonary congestion, and Hypoxia. Autopsy results also reported that it could have been seizure induced cardiac dysrhythmia leading to death. Patient's multiple concurrent	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							medical conditions remains a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 16-Mar-2022: Significant follow contains, lab data updated, autopsy results and cause of death updated as per report. Additional events added, cerebral edema, pulmonary edema, probable seizures with a fatal outcome, and unresponsive event deleted as per medical reviewer suggestion.	
[redacted]	ITALY	Abdominal distension, Asthenia, Cardiac arrest, Chest discomfort, Confusional state, Headache, Insomnia, Nausea, Vomiting	72.00	Female	Nicotine dependence(H); Bronchitis chronic(H); Cachexia(H); Pain(H); Anxiety(H); Eating disorder(H); Back pain(H); Depression(C); Toxic nodular goitre(H)	DUROGESIC; FOSTERA; TAPAZOLE; PARACETAMOLO; MOVICOLON; OMEPRAZOLE; ZOLOFT; DIBASE; XANAX; HALCION	This case was received via European Medicines Agency (Reference number [redacted] on 15-Jan-2022 and was forwarded to Moderna on 15-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of CARDIAC ARREST (Vaccination on 22.12.2021 with Spikevax (0.25 ml). In the following days marked headache, insomnia, asthenia, confusion states. On 28.12.21 at 10.00 am retrosternal weight, nausea, vomiting at 1pm ACC), CHEST DISCOMFORT (Vaccination on 22.12.2021 with Spikevax (0.25 ml). In the following days marked headache, insomnia, asthenia, confusion states. On 28.12.21 at 10.00 am retrosternal weight, nausea, vomiting at 1pm ACC), ABDOMINAL DISTENSION (Vaccination on 22.12.2021 with Spikevax (0.25 ml). In the following days marked headache, insomnia, asthenia, confusion states. On 28.12.21 at 10.00 am retrosternal weight, nausea, vomiting at 1pm ACC), INSOMNIA (Vaccination on 22.12.2021 with Spikevax (0.25 ml). In the following days marked headache, insomnia, asthenia, confusion states. On 28.12.21 at 10.00 am retrosternal weight, nausea, vomiting at 1pm ACC), CONFUSIONAL STATE (Vaccination on 22.12.2021 with Spikevax (0.25 ml). In the following days marked headache, insomnia, asthenia, confusion states. On 28.12.21 at 10.00 am retrosternal weight, nausea, vomiting at 1pm ACC), ASTHENIA (Vaccination on 22.12.2021 with Spikevax (0.25 ml). In the following days marked headache, insomnia, asthenia, confusion states. On 28.12.21 at 10.00 am retrosternal weight, nausea, vomiting at 1pm ACC), HEADACHE (Vaccination on 22.12.2021 with Spikevax (0.25 ml). In the following days marked headache, insomnia, asthenia, confusion states. On 28.12.21 at 10.00 am retrosternal weight, nausea, vomiting at 1pm ACC), VOMITING (Vaccination on 22.12.2021 with Spikevax (0.25 ml). In the following days marked headache, insomnia, asthenia, confusion states. On 28.12.21 at 10.00 am retrosternal weight, nausea, vomiting at 1pm ACC) and NAUSEA (Vaccination on 22.12.2021 with Spikevax (0.25 ml). In the following days marked headache, insomnia, asthenia, confusion states. On 28.12.21 at 10.00 am retrosternal weight, nausea, vomiting at 1pm ACC) in a 72-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3006322) for COVID-19 vaccination. The patient's past medical history included Tabaquism, Obstructive chronic bronchitis, Cachexia, Chronic pain, Anxiety, Eating disorder, Lumbago and Toxic nodular goitre. Concurrent medical conditions included Depression.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							Concomitant products included FENTANYL (DUROGESIC) from 14-Jul-2021 to 28-Dec-2021 for Ache, FLUOXETINE HYDROCHLORIDE, OLANZAPINE (FOSTERA) from 25-Jan-2019 to 28-Dec-2021 for Bronchitis chronic, SERTRALINE HYDROCHLORIDE (ZOLOFT) from 06-Aug-2021 to 28-Dec-2021 for Depression, THIAMAZOLE (TAPAZOLE) from 07-Jul-2017 to 28-Dec-2021 for Hyperthyroidism, PARACETAMOL (PARACETAMOLO) from 01-Dec-2021 to 28-Dec-2021, MACROGOL, POTASSIUM CHLORIDE, SODIUM BICARBONATE, SODIUM CHLORIDE (MOVICOLON) from 25-Jul-2017 to 28-Dec-2021, OMEPRAZOLE from 01-Dec-2021 to 28-Dec-2021, COLECALCIFEROL (DIBASE) from 12-Mar-2018 to 28-Dec-2021, ALPRAZOLAM (XANAX) from 16-Apr-2021 to 28-Dec-2021 and TRIAZOLAM (HALCION) from 20-Oct-2021 to 28-Dec-2021 for an unknown indication. On 22-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On 23-Dec-2021, the patient experienced CARDIAC ARREST (Vaccination on 22.12.2021 with Spikevax (0.25 ml). In the following days marked headache, insomnia, asthenia, confusion states. On 28.12.21 at 10.00 am retrosternal weight, nausea, vomiting at 1pm ACC) (seriousness criteria death and medically significant), CHEST DISCOMFORT (Vaccination on 22.12.2021 with Spikevax (0.25 ml). In the following days marked headache, insomnia, asthenia, confusion states. On 28.12.21 at 10.00 am retrosternal weight, nausea, vomiting at 1pm ACC) (seriousness criterion death), ABDOMINAL DISTENSION (Vaccination on 22.12.2021 with Spikevax (0.25 ml). In the following days marked headache, insomnia, asthenia, confusion states. On 28.12.21 at 10.00 am retrosternal weight, nausea, vomiting at 1pm ACC) (seriousness criterion death), INSOMNIA (Vaccination on 22.12.2021 with Spikevax (0.25 ml). In the following days marked headache, insomnia, asthenia, confusion states. On 28.12.21 at 10.00 am retrosternal weight, nausea, vomiting at 1pm ACC) (seriousness criterion death), CONFUSIONAL STATE (Vaccination on 22.12.2021 with Spikevax (0.25 ml). In the following days marked headache, insomnia, asthenia, confusion states. On 28.12.21 at 10.00 am retrosternal weight, nausea, vomiting at 1pm ACC) (seriousness criterion death), ASTHENIA (Vaccination on 22.12.2021 with Spikevax (0.25 ml). In the following days marked headache, insomnia, asthenia, confusion states. On 28.12.21 at 10.00 am retrosternal weight, nausea, vomiting at 1pm ACC) (seriousness criterion death), HEADACHE (Vaccination on 22.12.2021 with Spikevax (0.25 ml). In the following days marked headache, insomnia, asthenia, confusion states. On 28.12.21 at 10.00 am retrosternal weight, nausea, vomiting at 1pm ACC) (seriousness criterion death), VOMITING (Vaccination on 22.12.2021 with Spikevax (0.25 ml). In the following days marked headache, insomnia, asthenia, confusion states. On 28.12.21 at 10.00 am retrosternal weight, nausea, vomiting at 1pm ACC) (seriousness criterion death) and NAUSEA (Vaccination on 22.12.2021 with Spikevax (0.25 ml).	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							In the following days marked headache, insomnia, asthenia, confusion states. On 28.12.21 at 10.00 am retrosternal weight, nausea, vomiting at 1pm ACC) (seriousness criterion death). The patient died on 28-Dec-2021. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Treatment medication were not reported. Company Comment - This regulatory authority case concerns a 72 year old female patient with medical history of obstructive chronic bronchitis and cachexia who experienced the serious unexpected events of cardiac arrest, chest discomfort, abdominal distension, insomnia, asthenia, headache, vomiting and nausea. The events occurred between 1 day and 6 days after a dose of mRNA-1273 vaccine. The outcome was fatal, with death occurring 5 days after the onset of the events. Patient's medical history of obstructive chronic bronchitis and cachexia remains a confounder. The rechallenge was not applicable. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 17-Jan-2022: Follow-up received and contains no new information. On 28-Jan-2022: Follow up document received contains no new information On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 14-Jan-2022. On 13-Jun-2022: Due to incorrect follow-up receipt date in live follow-up, this case is amended to reflect the actual follow-up receipt date/Date FU Received by Safety in the narrative. This case was submitted on-time based on previous significant follow-up/initial. The actual follow-up receipt date/ Date FU Received by Safety for this case is 14-Jan-2022.	
[redacted]	FRANCE	Vaccination failure	64.00	Female	Sleep apnoea syndrome(C); Myocardial infarction(C); Cardiac failure(C); Ex-tobacco user(C); Angioplasty; Essential hypertension(C); Dyspnoea(C); Obesity(C);	0	This case was received via European Medicines Agency (Reference number: [redacted] on 18-Jan-2022 and was forwarded to Moderna on 18-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of VACCINATION FAILURE (Vaccination failure) in a 64-year-old female patient who received mRNA-1273 (Spikevax) (batch nos. 3002616 and 214009) for COVID-19 vaccination. The patient's past medical history included Angioplasty in 2002. Concurrent medical conditions included Sleep apnoea syndromes, Anterior myocardial infarction in 2002, Cardiac failure, Cessation	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
					Cardiac aneurysm(C)		of smoking, Essential hypertension, Dyspnea, Obesity and Cardiac aneurysm. On 02-Jun-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 22-Jul-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient experienced VACCINATION FAILURE (Vaccination failure) (seriousness criterion death). The patient died on 27-Dec-2021. The reported cause of death was covid pneumonia / vaccination failure. An autopsy was not performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided by reporter. Treatment information was not provided. Most recent FOLLOW-UP information incorporated above includes: On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 17-Jan-2022.	
[redacted]	FRANCE	Respiratory distress	64.00	Male	Asthma(C); Venous thrombosis limb(H)	0	This case was received via European Medicines Agency (Reference number: [redacted]on 18-Jan-2022 and was forwarded to Moderna on 18-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of RESPIRATORY DISTRESS (Distress respiratory) in a 64-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 018G21A) for COVID-19 vaccination. The patient's past medical history included Venous thrombosis limb (Asthma treated with Ventolin occasionally Lower limb venous thrombosis in 1996, 2012. No other medical/surgical history) in 2012. Concurrent medical conditions included Asthma (Asthma treated with Ventolin occasionally Lower limb venous thrombosis in 1996, 2012. No other medical/surgical history). On 19-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced RESPIRATORY DISTRESS (Distress respiratory) (seriousness criterion death). The patient died on 24-Dec-2021. An autopsy was not performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 23-Dec-2021, SARS-CoV-2 test: negative (Negative) Negative.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. Concomitant product use was not provided by the reporter. Treatment information was not provided. Company comment: This case concerns a 64-year-old male patient, with reported medical history of Asthma and Venous thrombosis limb (two events), who experienced the unexpected fatal event of Respiratory distress. The event occurred on an unknown date after the administration of an unknown dose of the mRNA-1273 vaccine. The report states that the patient died on December 24th but no further information on circumstances leading to the fatal outcome, cause of death or autopsy report was disclosed. The event was assessed by the reporter with the seriousness criteria of Fatal. Reported medical history of asthma and Venous thrombosis limb remains as confounders for the event. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	
[redacted]	GERMANY	Death	89.00	Female	Bronchial carcinoma(C); COVID-19(H); Chronic obstructive pulmonary disease(C); Diabetes mellitus(C); Pulmonary resection(C); Pulmonary embolism(H)	0	This case was received via European Medicines Agency (Reference number [redacted] on 20-Jan-2022 and was forwarded to Moderna on 20-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of DEATH (Unknown cause of death) in an 89-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 045921A) for COVID-19 vaccination. The patient's past medical history included COVID-19 in December 2020 and Lung embolism. Concurrent medical conditions included Bronchial carcinoma, COPD, Diabetes mellitus and Partial lung resection. On 21-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. Death occurred on 22-Dec-2021 The patient died on 22-Dec-2021. The cause of death was not reported. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant medications were not provided. Treatment information was not provided. Company Comment: This regulatory case concerns an 89-year-old, female patient with medical history of Bronchial carcinoma, Chronic Obstructive Pulmonary Disease (COPD), Diabetes Mellitus (DM), and status post Partial Lung resection (indication	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							not specified), who experienced the unexpected, serious event of death. The event occurred 1 day after administration of an unspecified dose of the Moderna mRNA-1273 vaccine. No further details were provided and the cause of death was unknown. The medical history of Bronchial carcinoma, COPD, DM and Partial Lung resection remain as confounders. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report.	
[redacted]	FRANCE	Cardio-respiratory arrest, Myocardial infarction	83.00	Female	Atrial fibrillation(C); Myocardial ischaemia(C); Hypertension(C); Dyslipidaemia(C)	0	This case was received via European Medicines Agency (Reference number: [redacted] on 20-Jan-2022 and was forwarded to Moderna on 20-Jan-2022. This regulatory authority case was reported by a pharmacist and describes the occurrence of CARDIO-RESPIRATORY ARREST (Cardio-respiratory arrest) and MYOCARDIAL INFARCTION (Myocardial infarct) in an 83-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Concurrent medical conditions included AFib, Ischaemic heart disease, Hypertension arterial and Dyslipidaemia. On 21-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 22-Dec-2021, the patient experienced CARDIO-RESPIRATORY ARREST (Cardio-respiratory arrest) (seriousness criteria death and medically significant) and MYOCARDIAL INFARCTION (Myocardial infarct) (seriousness criterion death). The patient died on 24-Dec-2021. The reported cause of death was Cardio-respiratory arrest and Myocardial infarction. An autopsy was not performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. No treatment details were reported. Company comment: This case concerns an 83-year-old female patient with relevant medical history of Atrial Fibrillation, Ischaemic heart disease, Hypertension arterial and Dyslipidaemia, who experienced serious unexpected events of Cardio-respiratory arrest and Myocardial infarction. The events occurred one day after the patient had received the mRNA-1273 vaccine. The patient died two days after the occurrence of the events and both events were reported with fatal outcome. No further information was provided. An autopsy was not performed. The patient's underlying medical history of Atrial Fibrillation, Ischaemic heart disease, Hypertension arterial and Dyslipidaemia remains a major confounding factor for the reported events. The rechallenge was not applicable having in mind that the patient died. The patient's elderly age remains additional confounding factor. The benefit-risk relationship of mRNA-1273 is not affected by this report.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
[redacted]	GERMANY	Death, General physical health deterioration, Hypophagia, Mobility decreased	63.00	Female	Osteoporosis(H); Gastrooesophageal reflux disease(H); Coagulopathy(H); Chronic obstructive pulmonary disease(H); Hepatic cirrhosis(H)	0	This case was received via European Medicines Agency (Reference number: [redacted] on 20-Jan-2022 and was forwarded to Moderna on 20-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (patient with pre-existing conditions after 3rd vaccination very rapid deterioration of general condition, reduced food and fluid balance.) in a 63-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Osteoporosis since an unknown date, Reflux oesophagitis since an unknown date, Coagulation disorder since an unknown date, COPD since an unknown date and Hepatic cirrhosis since an unknown date. On 09-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 09-Dec-2021, the patient experienced GENERAL PHYSICAL HEALTH DETERIORATION (patient with pre-existing conditions after 3rd vaccination very rapid deterioration of general condition, reduced food and fluid balance.), MOBILITY DECREASED (patient with pre-existing conditions after 3rd vaccination very rapid deterioration of general condition, reduced food and fluid balance.) and HYPOPHAGIA (patient with pre-existing conditions after 3rd vaccination very rapid deterioration of general condition, reduced food and fluid balance.). The patient died on 31-Dec-2021. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, GENERAL PHYSICAL HEALTH DETERIORATION (patient with pre-existing conditions after 3rd vaccination very rapid deterioration of general condition, reduced food and fluid balance.), MOBILITY DECREASED (patient with pre-existing conditions after 3rd vaccination very rapid deterioration of general condition, reduced food and fluid balance.) and HYPOPHAGIA (patient with pre-existing conditions after 3rd vaccination very rapid deterioration of general condition, reduced food and fluid balance.) had not resolved. No Concomitant medications were provided. No Treatment information was provided. No Information on risk factors or pre-existing conditions COPD, osteoporosis, cirrhosis of the liver, pronounced coagulation disorder, reflux esophagitis. After the 3rd vaccination with Moderna vaccine, the patient felt very tired/floppy and was in bed for 3 days. General condition immediately deteriorated. From 23-Dec-2021 Hardly to none food fluid intake, little to none movement, pain all over the body, at the end of strength; full care case for 9 days at the final stage. On 31-Dec- 2021 Death occurred.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							Company Comment:This is a regulatory case concerning a 63-year-old, female patient with relevant medical history of osteoporosis, reflux esophagitis, coagulation disorder, COPD and hepatic cirrhosis, who experienced the unexpected Fatal event of Unknown cause of death. The event occurred on 31-Dec-21, 23 days after the third dose of mRNA-1273 vaccine administered on 9-Dec-21 for the indication of COVID-19 vaccination. After vaccination patient felt very tired/floppy, was in bed for 3 days. From 23-Dec-21 there was significantly decreased food and fluid intake, minimal to no movement, pain all over the body, was a full care case for 9 days. It was unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The case was assessed as Serious as per Regulatory Authority report.	
[redacted]	GERMANY	Death	30.00	Male	Intellectual disability(C); Surgical vascular shunt	0	This case was received via European Medicines Agency (Reference number: [redacted] on 20-Jan-2022 and was forwarded to Moderna on 20-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (Found surprisingly dead in the morning. doctor suspected seizure, but relaxed posture, according to staff foam in front of mouth, persistent pale pink discharge from nose after death; 14 Tg after Moderna) in a 30-year-old male patient who received mRNA-1273 (Spikevax) (batch no. EX3599) for COVID-19 vaccination. The patient's past medical history included Surgical vascular shunt since 1992. Concurrent medical conditions included Mental handicap NOS. On 15-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. Death occurred on 02-Jan-2022 The patient died on 02-Jan-2022. The cause of death was not reported. It is unknown if an autopsy was performed. No concomitant medication information provided. No treatment medication information provided. As per the report, in neurosurgical surgery at the age of 1-2 Jahren, there was an intolerance to an antibiotic. 22.05.1991, physically and mentally disabled after premature birth due to listeriosis triple dissipation shunt system for about 29 Jahren 1st and 2nd vaccination with Biontech without abnormalities. The causality was provided as unclassifiable. Company Comment: This is a regulatory case concerning a 30-year-old, male patient with relevant medical history of Intellectual disability and Surgical vascular shunt, who experienced the unexpected Fatal event of Unknown cause of death. The event occurred on 2-Jan-22, 18 days after the third dose of mRNA-1273 vaccine administered on 15-Dec-21 for the indication of COVID-19 vaccination. It is unknown if an autopsy was performed. The	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The case was assessed as Serious as per Regulatory Authority report.	
[redacted]	GERMANY	Death	66.00	Male	Coronary artery disease(C); Coronary artery bypass	0	This case was received via European Medicines Agency (Reference number: [redacted] on 21-Jan-2022 and was forwarded to Moderna on 21-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (decease) in a 66-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Single bypass since an unknown date. Concurrent medical conditions included Coronary heart disease. On 18-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. Death occurred on 20-Dec-2021 The patient died on 20-Dec-2021. The reported cause of death was Sudden cardiac death. It is unknown if an autopsy was performed. No concomitant medication was provided. No treatment medication was provided. It was reported that -Are you or the person concerned aware of allergies? If yes, which one? no information on risk factors or pre-existing illnesses CHD; bypass/sudden cardiac death. Company comment: This is a fatal case from Regulatory Authority that concerns a 66-year-old male patient, with a medical history of Coronary heart disease and a single bypass, who experienced the unexpected fatal event of DEATH. He died two days after the third dose of the mRNA-1273. The cause of death was Sudden cardiac death. The history of Coronary heart disease and a single bypass remain as confounders. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 20-Jan-2022.	[redacted]
[redacted]	GERMANY	Cardiac arrest	90.00	Male	Cardiac failure(C)	0	This case was received via European Medicines Agency (Reference number: [redacted] on 21-Jan-2022 and was forwarded to Moderna on 21-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CARDIAC ARREST (Heart	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							condition) in a 90-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000117A) for COVID-19 vaccination. Concurrent medical conditions included Cardiac insufficiency. On 21-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 21-Dec-2021, the patient experienced CARDIAC ARREST (Heart condition) (seriousness criterion death). The patient died on 21-Dec-2021. The reported cause of death was Arrest cardiac. It is unknown if an autopsy was performed. No concomitant medication was reported. No treatment medications were reported. It was reported that information on risk factors or diseases included silicosis, heart failure / date of birth: 07.08.1931. Administration of the booster by the GP. After approx. 6 hours of sudden collapse with cardiac arrest. Attempted resuscitation attempts by emergency physician. Company Comment: This case concerns a 90-year-old male patient, with relevant medical history of Cardiac insufficiency, who experienced the unexpected serious event of Cardiac arrest. The event occurred on the same day after receiving the third dose of mRNA-1273 Vaccine which resulted in a fatal outcome. The patient's medical history of Cardiac insufficiency remain as a confounder for the occurrence of the event. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 20-Jan-2022.	
[redacted]	PORTUGAL	Myocarditis	31.00	Male	COVID-19(H); Chest pain(H)	0	This case was received via European Medicines Agency (Reference number: [redacted]-1722) on 21-Jan-2022 and was forwarded to Moderna on 21-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 31-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004498) for COVID-19 vaccination. The patient's past medical history included SARS-CoV-2 infection in September 2020 and Pain precordial in February 2021.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							On 15-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 28-Jul-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion death). The patient died on 28-Jul-2021. The reported cause of death was Myocarditis. An autopsy was performed. The autopsy-determined cause of death was Myocarditis. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2021, Chest X-ray: results not provided (Inconclusive) Results not provided. In 2021, Electrocardiogram: results not provided (Inconclusive) Results not provided. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered MYOCARDITIS (Myocarditis) to be probably related. No Concomitant medication provided. No treatment medication reported. Company comment: This fatal regulatory authority case concerns a 31-year-old male patient with relevant medical history of SARS-CoV-2 infection in September 2020 and Pain precordial in February 2021, who experienced serious expected AESI of myocarditis. The event occurred approximately 13 days after the 1st dose of the mRNA-1273. Reportedly, the patient suddenly passed away with autopsy reported myocarditis as the cause of death. The rechallenge was not applicable due to fatal outcome of the event. The patient's relevant medical history is a possible confounder. The benefit-risk relationship of mRNA-1273 is not affected by this report. The seriousness assessment as per regulatory authority. It was reported that 31 years old patient with COVID-19 on Sep 2020, on Feb 2021 patient complained of precordial pain with normal chest x-ray, however patient did not mention symptomatology again. On 15-07-2021 patient received Moderna vaccine (1st dose) and on 28-07-2021 patient died suddenly. The DIAP report reveals that the cause of death was emphatic myocarditis. Most recent FOLLOW-UP information incorporated above includes: On 21-Jan-2022: Translation received on 23-JAN-2022 which contains information on causality. On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 20-Jan-2022.	
[redacted]	GERMANY	Death	90.00	Female	COMIRNATY; Dementia(C)	0	This case was received via European Medicines Agency (Reference number: [redacted] on 21-Jan-2022 and was forwarded to Moderna on 21-Jan-2022.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (cause of death unknown) in a 90-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Previously administered products included for Prophylactic vaccination: Comirnaty BNT162b2 on 25-Nov-2021. Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2. Concurrent medical conditions included Dementia. On 30-Nov-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 4 dosage form. Death occurred on 01-Dec-2021 The patient died on 01-Dec-2021. The cause of death was not reported. It is unknown if an autopsy was performed. Concomitant drugs were not reported. Treatment medications were not provided. It was reported that on 25-Nov-2021 patient had third booster with biontech and on 30-Nov-2021 patient had fourth boosting with Moderna vaccine. Company comment: This Regulatory authority case concerns a 90-year-old, female patient, with medical history of dementia, who experienced the unexpected, serious (fatal) event of death. The event occurred 1 day after receiving a dose of mRNA-1273 vaccine, considered as the fourth dose of her COVID-19 vaccination schedule. It was reported that the patient received a third boosting dose in a hospital 5 days prior vaccination with mRNA-1273 vaccine at the same hospital. Due to underlying condition, it was reported that she could not say she had already been vaccinated with the booster dose. The patient died 1 day after vaccination and the cause of death was reported as unknown. Autopsy report is not available. The medical history of dementia remains as a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 20-Jan-2022.	
[redacted]	AUSTRIA	Cardiac arrest, Chills, Pyrexia	80.00	Male	Bedridden(C); Myocardial infarction(H); Hip surgery; Hip	ELIQUIS; OLEOVIT A; ANXIOLIT; LASIX P; SERTRALINE A; DOXYCYCLINE RIA;	This case was initially received via European Medicines Agency (Reference number [redacted] on 21-Jan-2022. The most recent information was received on 09-Feb-2022 and was forwarded to Moderna on 09-Feb-2022.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
					surgery; Cardiac pacemaker insertion; Decreased immune responsiveness(C); Medical device site joint infection(H)	TRITTICO; RISPERIDONA; PANTOPRAZOLE; MOLAXOLE; HYDAL; HYDAL; BISOPROLOL EG	This regulatory authority case was reported by a consumer and describes the occurrence of CARDIAC ARREST (cardiovascular arrest), PYREXIA (39.2 Fever) and CHILLS (chills) in an 80-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005897) for COVID-19 vaccination. The patient's past medical history included Myocardial infarction (Patient had a heart attack 7 years ago) in 2015, Medical device site joint infection (bedridden due to missing hip joint), Hip surgery (bedridden due to missing hip joint) in 2020, Hip surgery (bedridden due to missing hip joint. Patient had a hip surgery 3 years ago and unfortunately got a germ there, which was why hip was removed and was bedridden since then. Patient mother cared for it and a care aid came by every day.) and Cardiac pacemaker insertion (pacemakers). Concurrent medical conditions included Bedridden (bedridden due to missing hip joint) and Decreased immune responsiveness (Weakened immune system). Concomitant products included APIXABAN (ELIQUIS), RETINOL PALMITATE (OLEOVIT A), OXAZEPAM (ANXIOLIT), FUROSEMIDE (LASIX P), SERTRALINE HYDROCHLORIDE (SERTRALINE A), DOXYCYCLINE HYDROCHLORIDE (DOXYCYCLINE RIA), TRAZODONE HYDROCHLORIDE (TRITTICO), RISPERIDONE (RISPERIDONA), PANTOPRAZOLE, MACROGOL 3350, POTASSIUM CHLORIDE, SODIUM BICARBONATE, SODIUM CHLORIDE (MOLAXOLE), HYDROMORPHONE HYDROCHLORIDE (HYDAL), HYDROMORPHONE HYDROCHLORIDE (HYDAL) and BISOPROLOL FUMARATE (BISOPROLOL EG) for an unknown indication. On 20-Dec-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 21-Dec-2021, the patient experienced PYREXIA (39.2 Fever) (seriousness criterion medically significant) and CHILLS (chills) (seriousness criterion medically significant). On 22-Dec-2021, the patient experienced CARDIAC ARREST (cardiovascular arrest) (seriousness criterion death). The patient died on 22-Dec-2021. An autopsy was not performed. At the time of death, PYREXIA (39.2 Fever) and CHILLS (chills) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 10-Nov-2021, Bacterial test: 201 Bacteria urine. On 10-Nov-2021, Blood creatinine: 1.52 (High) 1.52 mg/dl (0.72-1.25). On 10-Nov-2021, Blood uric acid: 9.1 (High) 9.1 mg/dl (3.5-7.2). On 10-Nov-2021, C-reactive protein: 1.20 (High) 1.20 mg/dl (0-0.50). On 10-Nov-2021, Glomerular filtration rate: 44 (Low) 44 ml/min (>60). On 10-Nov-2021, Haematocrit: 38.4 38.4%. On 10-Nov-2021, Platelet count: 182 182. On 10-Nov-2021, White blood cells urine: 206 206.	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							On 12-Nov-2021, Alanine aminotransferase: <6 u/l (normal) <6 U/l (0-50). On 12-Nov-2021, Blood calcium: 2.29 (normal) 2.29 mmol/l (2.05-2.60). On 12-Nov-2021, Blood iron: 72 (normal) 72µg/dl (65-175). On 12-Nov-2021, Blood sodium: 129 (Low) 129 mmol/l (136-145). On 12-Nov-2021, Glycosylated haemoglobin: 5.1% , 33mmol/mol 5.1% , 33mmol/mol. On 12-Nov-2021, Low density lipoprotein: 107 107 mg/dl. On 12-Nov-2021, Prostatic specific antigen: 0.57 (normal) 0.57 µg/l (0-6.5). On 12-Nov-2021, Rheumatoid factor: <10 ku/l <10 kU/l (0-30). On 12-Nov-2021, SARS-CoV-2 antibody test: 121.08 121.08 construction/ml (normal value from 7.1 positive). On 12-Nov-2021, Serum ferritin: 472.9 (abnormal) 472.9 µg/l (21.8-27.5). On 12-Nov-2021, Transferrin: 1.44 (Low) 1.44 g/l (1.74-3.64). On 12-Nov-2021, Transferrin saturation: 35.50 (normal) 35.50% (16-45) and 35.50 (normal) 35.50% (16-45). The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. The patient died on 22-Dec-2021 at 03:00. Treatment medication was not provided by the reporter. Company Comment: This Fatal Regulatory Authority case concerns a 80-year-old, male patient, with medical history of decreased immune responsiveness, medical device joint infection, myocardial infarction, pace maker user and bedridden, who experienced the unexpected, serious (death) event of cardiac arrest, among others. The patient developed pyrexia and chills 1 day after receiving a the first dose of mRNA-1273 vaccine, complicated with cardiac arrest and died 2 days after vaccination. Complementary tests with date of approximately 1 months and 8 days prior vaccination evidenced sodium of 129 mmol, white blood cell urine 206 (no units), C-reactive protein 1.20 mg/dl, creatinine 1.52 mg/dl, ferritin 472.9 mcg/l. Cause of death was not reported. Autopsy report is not available. Patient's age, gender, medical history of decreased immune responsiveness, medical device joint infection, myocardial infarction, pace maker user, bedridden and polypharmacy remain as confounders. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 09-Feb-2022: Significant follow-up received included added lab tests and updated concomitant medication details. On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							based on the actual initial receipt date. The actual initial receipt date for this case is 20-Jan-2022.	
[redacted]	FRANCE	Cardiac arrest	86.00	Female	Cardiac valve disease(C); Depression(H); Hypertension(C)	0	This case was received via European Medicines Agency (Reference number: [redacted] on 21-Jan-2022 and was forwarded to Moderna on 21-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of CARDIAC ARREST (Malaise) in an 86-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 018G21A) for COVID-19 vaccination. Co-suspect product included non-company product CIPROFLOXACIN (CIFLOXA) for Urinary infection. The patient's past medical history included Anxiety depression. Concurrent medical conditions included Cardiac valve disease and Hypertension arterial. On 04-Jan-2022, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. In January 2022, the patient started CIPROFLOXACIN (CIFLOXA) (unknown route) at an unspecified dose. On an unknown date, after starting mRNA-1273 (Spikevax), the patient experienced CARDIAC ARREST (Malaise) (seriousness criterion death). The patient died on 05-Jan-2022. The reported cause of death was Arrest cardiac. An autopsy was not performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant Medication use information was not provided by reporter. Treatment Medication use information was not provided by reporter. Company comment This is a regulatory case concerning a 86-year-old female patient with medical history of Cardiac valve disease and Hypertension arterial, who experienced death with the Fatal unexpected, according to CCDS, event of cardiac arrest. The event occurred on an unknown date after the first dose of mRNA-1273 vaccine. The patient died on 05-Jan-2022. The reported cause of death was Arrest cardiac. An autopsy was not performed. The medical history of Cardiac valve disease and Hypertension arterial remains a confounder. The rechallenge was not applicable due to the fatal outcome. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 20-Jan-2022.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
[redacted]	NETHERLANDS	Abdominal pain, Blood glucose fluctuation, Circulatory collapse, Diarrhoea, Gastrointestinal pain, Haematochezia, Headache, Rectal haemorrhage, Resuscitation, Sinusitis, Vomiting	77.00	Female	Pancreatitis(H); Obesity(H); Radius fracture(H); Dyspnoea(H); Type 1 diabetes mellitus(H); Trigger finger(H); Cholangitis(H); Tibia fracture(H); Tendon sheath incision(H); Agoraphobia(H); Cholelithiasis(H); PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE; Hypertension(C); Neurolysis	AZITROMYCINE; INSULIN; HYDROCHLOORTHIAZIDE	This case was initially received via European Medicines Agency (Reference number: [redacted] on 22-Jan-2022. The most recent information was received on 11-Mar-2022 and was forwarded to Moderna on 11-Mar-2022. This regulatory authority case was reported by a physician and describes the occurrence of RESUSCITATION (19/12/2021 19 hr: collapsed, CPR), RECTAL HAEMORRHAGE (19/12/2021, 6.38 am: a lot of rectal blood loss), CIRCULATORY COLLAPSE (19/12/2021 19 hr: collabed, resuscitation) and ABDOMINAL PAIN (19/12/2021 06.38 hr: Abdominal pain; seen on SEH, suspected GE/food poisoning of spoiled fish.) in a 77-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Pancreatitis in 2001, Morbid obesity (BMI 36.8, lost 5 kg compared to the year before) in 2021, Fracture of head of radius, open (Distal radius fracture left) in 1989, Dyspnoea (Been ill with dyspnea and fever in early and mid-2020. At the time, testing was not available usual. Restored without AB usage. May have been Covid, but can no longer be traced) in 2020, Type 1 diabetes mellitus in 1991, Trigger finger in 2009, Cholangitis in 2006, Tibia fracture (lower leg fracture right) in 1986, Trigger finger release (there was no family history) in 2009, Agoraphobia (supervised by POH GGZ), Gallstones (ERCP with papillotomy, cholecystectomy) in 1996 and Neurolysis (Release N medianus right, April 2014: neurolysis without operating microscope or loupe magnification) in 2014. Previously administered products included for Drug use for unknown indication: COVID-19 vaccine Pfizer COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST on 14-Apr-2021, COVID-19 vaccine Pfizer COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST on 20-May-2021. Past adverse reactions to the above products included No adverse event with COVID-19 vaccine Pfizer COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST, COVID-19 vaccine Pfizer COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST. Concurrent medical conditions included Hypertension. Concomitant products included AZITHROMYCIN (AZITROMYCINE) from 17-Dec-2021 to an unknown date for Sinusitis, INSULIN and HYDROCHLOORTHIAZIDE for an unknown indication. On 13-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 17-Dec-2021, the patient experienced BLOOD GLUCOSE FLUCTUATION (17/12 GP consulted for sinus complaints, glucose fluctuations and headache), HEADACHE (17/12 GP consulted for sinus symptoms, glucose fluctuations and headaches) and SINUSITIS (17/12 GP consulted for sinus symptoms, glucose fluctuations and headaches). On 18-Dec-2021, the patient experienced	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							VOMITING (18/12/21, 21 hr: abdominal pain, diarrhea and vomiting), DIARRHOEA (18/12/21, 9:00 pm: abdominal pain, diarrhea and vomiting), GASTROINTESTINAL PAIN (18/12/21, 9:00 pm: abdominal pain, diarrhea and vomiting) and ABDOMINAL PAIN (19/12/2021 06.38 hr: Abdominal pain; seen on SEH, suspected GE/food poisoning of spoiled fish.) (seriousness criterion death). On 19-Dec-2021, the patient experienced RESUSCITATION (19/12/2021 19 hr: collapsed, CPR) (seriousness criterion death), RECTAL HAEMORRHAGE (19/12/2021, 6.38 am: a lot of rectal blood loss) (seriousness criterion death), HAEMATOCHEZIA (19/12/2021 06.38 hr: stomach ache; seen at ED, suspected GE/food poisoning from spoiled fish. Some blood in faeces) and CIRCULATORY COLLAPSE (19/12/2021 19 hr: collabed, resuscitation) (seriousness criterion death). The patient died on 19-Dec-2021. The reported cause of death was a lot of rectal bleeding. An autopsy was not performed. At the time of death, HAEMATOCHEZIA (19/12/2021 06.38 hr: stomach ache; seen at ED, suspected GE/food poisoning from spoiled fish. Some blood in faeces), BLOOD GLUCOSE FLUCTUATION (17/12 GP consulted for sinus complaints, glucose fluctuations and headache), VOMITING (18/12/21, 21 hr: abdominal pain, diarrhea and vomiting), DIARRHOEA (18/12/21, 9:00 pm: abdominal pain, diarrhea and vomiting), HEADACHE (17/12 GP consulted for sinus symptoms, glucose fluctuations and headaches), SINUSITIS (17/12 GP consulted for sinus symptoms, glucose fluctuations and headaches) and GASTROINTESTINAL PAIN (18/12/21, 9:00 pm: abdominal pain, diarrhea and vomiting) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 14-Oct-2020, Physical examination: abnormal (abnormal) RR 134/55, MAP: 81.3, height 1.59 cm, weight 98 kg and normal (normal) BP 134/55, MAP: 81.3, height 1.59 cm, weight 98 kg. On 20-Apr-2021, Ophthalmological examination: normal (normal) left eye: no abnormalities, right eye: no abnormalities and normal (normal) left eye: no abnormalities, right eye: no abnormalities. On 13-Oct-2021, Glycosylated haemoglobin: 52 (normal) 52= high for non-diabetics, but well-set diabetic should have < 53, so ok.. On 13-Oct-2021, Laboratory test: abnormal (abnormal) Hb 7.4 (net te laag), HT 0.36 (LLN), MCV 88 fl, trombo's 252 (normal), leuko's 4.5 (normal), Natrium 141 (normal) , Kalium 4.3 (normal), and normal (normal) Hb 7.4 (net te laag), HT 0.36 (LLN), MCV 88 fl, trombo's 252 (normal), leuko's 4.5 (normal), Natrium 141 (normal) , Kalium 4.3 (normal). On 13-Oct-2021, Liver function test: abnormal (abnormal) ALAT 16, Cholesterol 3.5, HDL cholesterol 1.3, non-HDL cholesterol: 2.2 (= low) and low (Low) ALT 16, Cholesterol 3.5, HDL cholesterol 1.3, non- HDL cholesterol: 2.2 (= low). On 13-Oct-2021, Renal impairment: abnormal (abnormal) Kreatinine 105 (high, ULN: 100), EGFR (CKD-EPI): 44 = moderate renal impairment.	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							On 20-Oct-2021, Physical examination: abnormal (abnormal) RR 138/70, MAP: 92.7, height 1.59 cm, weight 93 kg, BMI 36.8 BSA 1.94 and normal (normal) BP 138/70, MAP: 92.7, height 1.59 cm, weight 93 kg, BMI 36.8 BSA 1.94. On 19-Dec-2021, Blood glucose: 16.7 (High) On SEH: 16.7. On 19-Dec-2021, Liver function test: abnormal (abnormal) on SEH: alk phosph 103 other liver enzymes not abnormal and 103 (normal) on emergency room: alk fosf 103 other liver enzymes not abnormal. On 19-Dec-2021, Physical examination: abnormal (abnormal) 0.38 hr on 19/12/2021: T 35.9, vivid intestinal peristalsis, pressure pain epigastrio upper left., abnormal (abnormal) 06.38 hr: RR 130/70, pols 77, sat 97%., normal (normal) 06.38 hr: RR 130/70, pols 77, sat 97%. and abnormal (abnormal) 00:38 am on 19/12/2021: T 35.9, vivid intestinal peristalsis,pressure pain epigastrio upper left.. On 19-Dec-2021, Renal impairment: abnormal (abnormal) SEH : eGFR 41 (was 44 2 months ago) , creatinine 111 (was 105 2 months ago). For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Additional information on azithromycin drug was as follow:Patient had sinus symptoms from +/- 1 dec for which she was using Otrivin. On 17/12 tel. consult informed "TC: persistent sinus symptoms, headaches and rising sugars. Patient had no fever, no rhinitis. Nasal spray does not help, Patient seen weekend and rising sugars yet blind cure: Patient took Azithromycin 500mg 1d1t, 3 dgn. No treatment medications were provided. Company comment: This regulatory authority case concerns a 77-year-old female patient, with medical history of Morbid obesity, hypertension, Type 1 diabetes Mellitus, and interchange of vaccine products (PFIZER COVID-19 vaccine), who experienced the serious (fatal), unexpected events of rectal hemorrhage, abdominal pain, circulatory collapse and resuscitation. The patient consulted a physician 4 days after receiving the dose of mRNA-1273 COVID-19 vaccine (3rd dose in the series) due to sinus complaints, glucose fluctuation and headaches. Five days after the vaccine, patient diarrhea, and gastrointestinal pain. Six days after the vaccine, patient had abdominal pain and was seen on SEH, she was suspected to have gastroenteritis/food poisoning due to spoiled fish. At SEH, blood glucose was 16.7 (no measurement unit) liver function test was abnormal, eGFR was decreased 41, on physical examination she had te	
[redacted]	NETHERLANDS	Myocardial infarction	80.00	Female	Atrial fibrillation(C); Diabetes mellitus(C); Obesity(C); Vertigo	METFORMINE [METFORMIN]; FRUSEMIDE [FUROSEMIDE]; ACENOCOUMAROL; INSULINE NPH;	This case was initially received via European Medicines Agency (Reference number: [redacted] on 22-Jan-2022. The most recent information was received on 11-Feb-2022 and was forwarded to Moderna on 11-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDIAL INFARCTION	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
					positional(C); Hypertension(C); Dizziness postural(C); Myocardial infarction(H); COMIRNATY; COMIRNATY	OMEPRAZOL A; ATORVASTATINE [ATORVASTATIN]; GLIMEPIRIDE; VALSARTAN; PAROXETIN [PAROXETINE]; METOPROLOL;MORPHINE; BARNIDIPINE	(myocardial infarction) in an 80-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Myocardial infarction in 2015. Previously administered products included for Product used for unknown indication: BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST on 18-Mar-2021, BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST on 26-Apr-2021. Past adverse reactions to the above products included No adverse reaction with BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST, BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST. Concurrent medical conditions included Atrial fibrillation, Diabetes mellitus, Obesity (BMI >32), Benign paroxysmal positional vertigo (Complaining of dizziness matching orthostasis and BPPD for a long time), Hypertension and Orthostatic dizziness (Complaining of dizziness matching orthostasis and BPPD for a long time). Concomitant products included METFORMIN (METFORMINE [METFORMIN]), FUROSEMIDE (FRUSEMIDE [FUROSEMIDE]), ACENOCOUMAROL, INSULIN ISOPHANE PORCINE (INSULINE NPH), OMEPRAZOLE (OMEPRAZOL A), ATORVASTATIN (ATORVASTATINE [ATORVASTATIN]), GLIMEPIRIDE, VALSARTAN, PAROXETINE (PAROXETIN [PAROXETINE]), METOPROLOL, MORPHINE (METOPROLOL;MORPHINE) and BARNIDIPINE for an unknown indication. On 02-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 05-Jan-2022, the patient experienced MYOCARDIAL INFARCTION (myocardial infarction) (seriousness criterion death). The patient died on 05-Jan-2022. The reported cause of death was myocardinfarct. An autopsy was not performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No treatment information was provided. Company comment: This is a regulatory authority case concerning a 80-year-old, female patient with relevant medical history of myocardial infarction and concurrent medical conditions of atrial fibrillation, diabetes mellitus, hypertension and obesity (BMI >32) and vaccine history of receiving 2 doses of another brand of Covid-19 vaccine (Covid-19 vaccine Comirnaty) as previous doses, who	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							experienced the unexpected, serious, AESI event of myocardial infarction. The event myocardial infarction occurred approximately 3 days after the unknown dose number of mRNA-1273 vaccine administration. The outcome of the event myocardial infarction was fatal. The reported cause of death was myocardial infarction. Autopsy was not performed. The medical history of myocardial infarction and concurrent medical conditions of atrial fibrillation, diabetes mellitus, hypertension and obesity remain confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 11-Feb-2022: Patient medical history added, autopsy details and concomitant drug details updated. On 11-Feb-2022: Translation document received on 17 FEB 2022 with event verbatim updated. On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 20-Jan-2022.	
[redacted]	GREECE	Chills, Coronary artery occlusion, Death, Dyspnoea, Fatigue, Feeling cold, Myocardial infarction, Pyrexia	73.00	Male	Hypertension(H); Diabetes mellitus(H)	0	This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDIAL INFARCTION (Myocardial infarction), DEATH (Death), CORONARY ARTERY OCCLUSION (Coronary occlusion), DYSPNOEA (Dyspnea) and the first episode of CHILLS (Shivers) in a 73-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Hypertension and Diabetes. On 22-Dec-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 22-Dec-2021, the patient experienced DYSPNOEA (Dyspnea) (seriousness criterion death) and the first episode of CHILLS (Shivers) (seriousness criterion death). On 23-Dec-2021, the patient experienced MYOCARDIAL INFARCTION (Myocardial infarction) (seriousness criterion death), DEATH (Death) (seriousness criterion death) and CORONARY ARTERY OCCLUSION (Coronary occlusion) (seriousness criteria death and medically significant). On an unknown date, the patient experienced FEELING COLD (Sensation of cold), PYREXIA (Fever), FATIGUE (Fatigue aggravated), FATIGUE (Fatigue) and the second episode of CHILLS (Shivers). The patient died on 23-Dec-2021. The reported cause of death was Coronary occlusion and Myocardial infarction. It is unknown if an autopsy was performed. At the time of death, FEELING COLD (Sensation of cold), PYREXIA (Fever), FATIGUE (Fatigue aggravated), FATIGUE (Fatigue) and the last episode of CHILLS (Shivers) outcome was unknown.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, COVID-19: infection covid-19 (Inconclusive) INFECTION COVID-19. Concomitant product was not provided by the reporter. No treatment information was provided. Patient had third dose of the vaccine (booster dose). This is a regulatory authority case concerning a 73-year-old, male patient with medical history of Hypertension and Diabetes, who experienced the unexpected fatal events of Myocardial infact, Death, Coronary artery occlusion, Dyspnea and Chills and unexpected non-serious event of feeling cold, and expected non-serious events of Pyrexia, fatigue, fatigue and chills. The events dyspnea, chills occurred the same day after the third dose of mRNA-1273 COVID 19 Vaccine. The events myocardial infarct, death and Coronary Artery Occlusion occurred 1 day after the third dose of mRNA-1273 COVID 19 Vaccine. The reported cause of death was Coronary occlusion and myocardial infarction. It is unknown if an autopsy was performed. The medical history of Hypertension and Diabetes remains a confounder. The benefit-risk relationship of mRNA-1273 COVID 19 Vaccine, is not affected by this report.	
[redacted]	JAPAN	Pneumonia aspiration, Respiratory failure	82.00	Male	Cardiac failure(C); Chronic obstructive pulmonary disease(C)	0	This case was received via Takeda Pharmaceuticals (Reference number: [redacted] on 24-Jan-2022 and was forwarded to Moderna on 26-Jan-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, [redacted]. The patient had COPD and was being placed on home oxygen therapy (HOT). On an unknown date, the patient received the 1st dose of a vaccine. On an unknown date, the patient received the 2nd dose of a vaccine. On an unknown date, body temperature before vaccination: 36.6 degrees Celsius. On 22-Jan-2022, at 15:00, the patient received the 3rd dose of this vaccine. On 23-Jan-2022, a decrease in SAT was observed at dawn, and the flow rate of HOT was increased. At 13:25, there was a poor improvement in symptoms and the patient died. Because the patient had COPD and heart failure, it is considered that aspiration pneumonia and deterioration of respiratory failure occurred. The outcome of aspiration pneumonia and deterioration of respiratory failure was reported as fatal. Follow-up investigation will be made. Company Comment: Although respiratory failure developed after the administration of ELASOMERAN, factors such as concurrent conditions may have also had an influence.	[redacted]
[redacted]	CROATIA	Agonal respiration, Death	93.00	Female	Cor pulmonale chronic(C); Chronic respiratory failure(C);	ATROVENT N; KALINORM; LEXILLIUM; NEBILET; RISSET;	This case was initially received via European Medicines Agency (Reference number: [redacted] on 27-Jan-2022. The most recent information was received on 17-Feb-2022 and was forwarded to Moderna on 17-Feb-2022.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
					Goitre(C); Scoliosis(C); Cholecystectomy; Hypertension(C); Delusion(C); VAXZEVRIA; VAXZEVRIA; Neurosis(H); OXYGEN(H)	FUROSEMIDA MK [FUROSEMIDE]	This regulatory authority case was reported by a physician and describes the occurrence of DEATH (Death) and AGONAL RESPIRATION (agonal breathing) in a 93-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3004952) for COVID-19 vaccination. The patient's past medical history included Unspecified neurotic disorder (F48 - other neurotic disorders) and Cholecystectomy (State following cholecystectomy). Previously administered products included for Product used for unknown indication: Vaxzevria 2nd dose (Vaxzevria 2nd dose (ABW4801)), Oxygen therapy and Vaxzevria 1st dose (Vaxzevria 1st dose (ABV4678)). Past adverse reactions to the above products included No adverse event with Oxygen therapy, Vaxzevria 1st dose and Vaxzevria 2nd dose. Concurrent medical conditions included Cor pulmonale chronic (Cor pulmonale chr. (I27.8)), Chronic respiratory failure (St post pneumonia I.dex. am II [State after right lung pneumonia 2 months ago] Insufficientio respiratoria globalis [Global respiratory failure] (J96.1)), Struma nodosa (Nodular goitre of the thyroid gland), Scoliosis (Scoliosis vertebrae thoracalis), Hypertension arterial (Arterial hypertension) and Organic delusional syndrome (Organic delusional disorder (F06.2)). Concomitant products included POTASSIUM CHLORIDE (KALINORM) for Chronic cor pulmonale, IPRATROPIUM BROMIDE (ATROVENT N) for Chronic respiratory failure, NEBIVOLOL HYDROCHLORIDE (NEBILET) and FUROSEMIDE (FUROSEMIDA MK [FUROSEMIDE]) for Cor pulmonale chronic, RISPERIDONE (RISSET) for Organic delusional syndrome, BROMAZEPAM (LEXILLIUM) for Unspecified neurotic disorder. On 27-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter once a day. On 28-Dec-2021, after starting mRNA-1273 (Spikevax), the patient experienced DEATH (Death) (seriousness criterion death) and AGONAL RESPIRATION (agonal breathing) (seriousness criterion death). The patient died on 28-Dec-2021. An autopsy was not performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered DEATH (Death) and AGONAL RESPIRATION (agonal breathing) to be unlikely related. No concomitant medications were reported No treatment information was provided. Sender's comment: It was reported that patient's medical record and death certificate were provided. The patient's underlying disease led to death and oxygen complications were also presented before 3rd dose of vaccine has been administered.	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							COMPANY COMMENT : This regulatory authority case concerns a 93-year-old, female patient with relevant medical history of Cor pulmonale chronic, Chronic respiratory failure , Oxygen therapy ,who had a fatal outcome with unexpected serious event of death (seriousness criterion Death) and agonal respiration (seriousness criterion Death) which occurred one day after third dose of mRNA-1273. The patient was noted to have received two doses with Vaxzevria unknown day prior to current vaccination with mRNA-1273 (Interchange of vaccine products). Medical history of relevant medical history of Cor pulmonale chronic, Chronic respiratory failure , Oxygen therapy remains as confounding. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting., Most recent FOLLOW-UP information incorporated above includes: On 17-Feb-2022: Follow-up included relevant past drug history, relevant past historical condition, concomitant medication, added autopsy details, sender's comments and reporter causality updated.	
[redacted]	ITALY	Cerebrovascular accident	81.00	Female	Hypertension(H); Diabetes mellitus(H)	0	This case was received via European Medicines Agency (Reference number: [redacted] on 28-Jan-2022 and was forwarded to Moderna on 28-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of CEREBROVASCULAR ACCIDENT (Right carotid dissection with stroke in middle right brain territory) in an 81-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Hypertension NOS and Diabetes. On 18-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) .5 milliliter. On 19-Dec-2021, the patient experienced CEREBROVASCULAR ACCIDENT (Right carotid dissection with stroke in middle right brain territory) (seriousness criterion death). The patient died on 19-Dec-2021. It is unknown if an autopsy was performed. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medications reported No treatment medications provided Company Comment: This case concerns a 81-year-old female patient with medical history of hypertension and diabetes reported, who experienced the serious unexpected event of Cerebrovascular accident with	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							fatal outcome. The event occurred on the day after a dose of mRNA-1273 received for COVID-19 Vaccination. It was reported that the patient experienced a right carotid dissection with stroke in middle right brain territory however very limited information regarding this event has been provided at this time and it is unknown if an autopsy was performed. The medical history of hypertension and diabetes as well as patient's advanced age remain as confounding risk factor. No concomitant medication or treatment information was reported. The benefit-risk relationship of COVID-19 Vaccine Moderna (mRNA-1273) is not affected by this report.	
[redacted]	GERMANY	Cardiac arrest, Pulmonary oedema	72.00	Female	Arrhythmia(H); Renal failure(H); Chronic obstructive pulmonary disease(H); SPIKEVAX(H)	0	This case was received via European Medicines Agency (Reference number: [redacted] on 28-Jan-2022 and was forwarded to Moderna on 28-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of PULMONARY OEDEMA (Lung oedema) and CARDIAC ARREST (Cardiac arrest) in a 72-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 000120A) for COVID-19 vaccination. The patient's past medical history included Cardiac arrhythmia, Renal insufficiency and COPD. Previously administered products included for COVID-19 vaccination: SPIKEVAX on 06-Dec-2021. Past adverse reactions to the above products included No adverse event with SPIKEVAX. On 04-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 2 dosage form. On 06-Jan-2022, the patient experienced PULMONARY OEDEMA (Lung oedema) (seriousness criterion death) and CARDIAC ARREST (Cardiac arrest) (seriousness criterion death). The patient died on 06-Jan-2022. The reported cause of death was Heart arrest. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant drug has been provided. No treatment drug has been provided. Company comment: This is a regulatory case concerning a 72-year-old, female patient with a history of Arrhythmia, Chronic obstructive pulmonary disease and Renal failure, who experienced the serious (fatal) unexpected, according CCDS, AESI of Pulmonary oedema and, the serious (fatal) unexpected, according CCDS, event of Cardiac arrest. The events occurred approximately 2 days after the mRNA-1273 vaccine, dose number not provided. It is unknown whether an autopsy was performed. The patient had a fatal outcome 2 days after vaccination. The rechallenge was not applicable due to the fatal outcome. The medical history of Arrhythmia, Chronic obstructive pulmonary disease and Renal failure remain as confounders. The	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	
[redacted]	JAPAN	Arrhythmia, Cardio-respiratory arrest, Myocardial infarction, Respiratory arrest	96.00	Female	Dementia(C); Gastritis(C); Cerebral infarction(H)	LANSOPRAZOLE; MEMANTINE HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE; EXCEGRAN; ENSURE H	This case was initially received via Takeda Pharmaceuticals (Reference number:[redacted] on 27-Jan-2022. The most recent information was received on 21-Feb-2022 and was forwarded to Moderna on 01-Mar-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref,[redacted]. On 21-Feb-2022, follow-up information was received from a physician. The patient was taking lansoprazole 15 mg for gastritis and also continuing to take zonisamide 100 mg as prescribed by a previous physician. On 26-Jul-2011, the patient started to take memantine hydrochloride 5 mg for dementia. On 29-Jul-2019, the patient started to take enteral nutrition 250 mL. On 27-Sep-2021, the patient started to take memantine hydrochloride 10 mg for dementia. On an unknown date, the patient received the 1st dose of a novel coronavirus vaccine (unknown product name). On an unknown date, the patient received the 2nd dose of a novel coronavirus vaccine (unknown product name). On an unknown date, body temperature before the vaccination: 36.1 degrees Celsius. On 26-Jan-2022, around 10:00, as the patients condition was normal, the 3rd vaccination with this vaccine was performed. On 27-Jan-2022, around 06:10, the patient did not have any significant changes and was in a sitting position in the living room. Around 06:15, a facility care staff found the patient in respiratory arrest. Cardiac massage was performed, but the patient did not recover. At 07:37, the patient was in cardio-respiratory arrest. The reporting hospital, which performed visiting medical examination, visited the patient's home and confirmed death. The symptoms were sudden onset and considered to be arrhythmia due to myocardial infarction. The cause of death was myocardial infarction. There were no abnormal findings in medical examination, and the relationship was unknown. Since the patient was old, the above measures were taken without the family members request for life-prolonging treatment. The outcome of respiratory arrest, cardio-respiratory arrest, arrhythmia, and myocardial infarction was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: The occurrence of adverse events is not related to concomitant drug because the patient was taking drugs for a long time and had no previous problems before. The patient was at an old age, and death is very likely to have been caused by sudden pain. Follow-up received on 21-FEB-2022 Updated: Patient Information, Other Relevant History, Product Information, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship. Company comment: The case concerns a 96-year-old female patient with medical history of cerebral infarction, who experienced unexpected fatal events of Myocardial infarction (AESI), cardio respiratory arrest, arrhythmia and Respiratory arrest. The events were considered serious per death and medically significant criteria. The events occurred approximately	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							1 day after the third dose of mRNA 1273 vaccine. As reported, a facility care staff found the patient in respiratory arrest. Cardiac massage was performed, but the patient did not recover and was in cardio-respiratory arrest. The reporting hospital, which performed visiting medical examination, visited the patient's home and confirmed death. The symptoms were with sudden onset and considered to be arrhythmia due to myocardial infarction. The cause of death was myocardial infarction, as reported. There were no abnormal findings in medical examination. The outcome of the events was reported as fatal. Patient's advanced age and prior history of cerebral infarction remain as confounders. The benefit risk relationship of vaccine is not affected by this report.	
[redacted]	GERMANY	Death, Fatigue, Influenza, Paraesthesia, Vomiting	81.00	Female	Heart valve calcification(C)	0	This case was received via European Medicines Agency (Reference number: [redacted] on 29-Jan-2022 and was forwarded to Moderna on 29-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (cause of death unknown) in an 81-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 000114AM) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Heart valve calcification. On 30-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 02-Jan-2022, the patient experienced FATIGUE (hot flashes, body aches, vomiting and a feeling as if electricity is being chased through the body. So exhausted that bedridden), PARAESTHESIA (hot flashes, body aches, vomiting and a feeling as if electricity is being chased through the body. So exhausted that bedridden), VOMITING (hot flashes, body aches, vomiting and a feeling as if electricity is being chased through the body. So exhausted that bedridden) and INFLUENZA (hot flashes, body aches, vomiting and a feeling as if electricity is being chased through the body. So exhausted that bedridden). The patient died on 07-Jan-2022. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, FATIGUE (hot flashes, body aches, vomiting and a feeling as if electricity is being chased through the body. So exhausted that bedridden), PARAESTHESIA (hot flashes, body aches, vomiting and a feeling as if electricity is being chased through the body. So exhausted that bedridden), VOMITING (hot flashes, body aches, vomiting and a feeling as if electricity is being chased through the body. So exhausted that bedridden) and INFLUENZA (hot flashes, body aches, vomiting and a feeling as if electricity is being chased through the body. So exhausted that bedridden) had not resolved. Treatment medication was not provided. No Information about risk factors or pre-existing conditions. A slightly calcified heart valve has been treated with medication.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							At the end of November 2021, a follow-up examination took place by cardiologists impression were nothing was noticeable. Patient was doing well before vaccination. After the booster she felt very bad after 2 days and after a week she died in bed at night. Company comment: This regulatory authority case concerns an 81-year-old female patient with no relevant medical history who experienced serious unexpected event of death, that occurred approximately 8 days after the booster dose of the mRNA-1273 . The rechallenge was not applicable due to occurrence after the booster dose and fatal outcome of the event. The cause of death was not reported. The patient had concurrent condition of calcification of heart valve however the most recent cardiologist consultation did not show anything significant. The benefit-risk relationship of mRNA-1273 is not affected by this report.	
[redacted]	GERMANY	Sudden death	65.00	Male	Coronary artery disease(H); Atrial fibrillation(H); Hypertension(H)	0	This case was received via European Medicines Agency (Reference number: [redacted]) on 01-Feb-2022 and was forwarded to Moderna on 01-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of SUDDEN DEATH (Sudden death unexplained) in a 65-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000105A) for COVID-19 vaccination. The patient's past medical history included Coronary disease, Atrial fibrillation and Arterial hypertension. On 05-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. The patient died on 06-Jan-2022. The cause of death was not reported. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No relevant concomitant medications were reported. No treatment information was provided. Company comment: This is a regulatory authority case concerning a 65-year-old male patient with a relevant medical history of coronary disease, atrial fibrillation and arterial hypertension, who experienced the serious unexpected event of sudden death. The event of sudden death occurred approximately 2 days after the booster dose of mRNA-1273 (Spikevax). The cause of death, clinical details, labs/diagnostic results and concomitant medications not reported. The medical history of coronary disease, atrial fibrillation complicated by arterial hypertension could be confounders. The benefit-risk relationship of mRNA-1273 (Spikevax) is not affected by this report.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
[redacted]	ITALY	Fatigue, Thrombosis, Vertigo	65.00	Female	Cardiac failure(C); Atrial fibrillation(C); Tricuspid valve incompetence(C)	0	This case was initially received via European Medicines Agency (Reference number: [redacted]on 01-Feb-2022. The most recent information was received on 03-Mar-2022 and was forwarded to Moderna on 03-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of FATIGUE (Strong fatigue and head turns, on 5 January she died due to cardiac intercameral thrombus.), VERTIGO (Strong fatigue and head turns, on 5 January she died due to cardiac intercameral thrombus.) and THROMBOSIS (Strong fatigue and head turns, on 5 January she died due to cardiac intercameral thrombus.) in a 65-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Concurrent medical conditions included Decompensation cardiac (DECOMPENSATION WITH SEVERE BIVENTRICULAR DYSFUNCTION. IN TP WITH ENTRESTO), Atrial fibrillation (DOES PERSISTENT PERMANENT WITH BIATRILE EXPANSION AND VALVE INSUFFICIENCIES THAT FROM MILD (4 YEARS AGO)) and Tricuspid insufficiency (SEVERE TRICUSPID INSUFFICIENCY). On 28-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .5 dosage form. On 29-Dec-2021, the patient experienced FATIGUE (Strong fatigue and head turns, on 5 January she died due to cardiac intercameral thrombus.) (seriousness criterion death), VERTIGO (Strong fatigue and head turns, on 5 January she died due to cardiac intercameral thrombus.) (seriousness criterion death) and THROMBOSIS (Strong fatigue and head turns, on 5 January she died due to cardiac intercameral thrombus.) (seriousness criterion death). It is unknown if an autopsy was performed. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. No concomitant medications were reported. No treatment drugs were reported. Company comment: This is a regulatory case concerning a 65-year-old female patient with a medical history of tricuspid insufficiency, atrial fibrillation and decompensation cardiac, who experienced the unexpected serious fatal events of Fatigue, Thrombosis and Vertigo one day after the unspecified dose of mRNA-1273 vaccine. It was reported that the patient experienced strong fatigue and head turns, and she died due to cardiac intercameral thrombus. Biatrial dilation and moderate valve insufficiencies, decompensation with severe bi ventricular dysfunction and atrial fibrillation (ECG) were also reported, which may suggest underlying medical	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							condition. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 03-Mar-2022: medical history were added and action taken updated to unknown. On 28-Mar-2022: Non Significant follow up received:Event verbatim updated On 22-Apr-2022: Follow-up received included updated events verbatim.	
[redacted]	UNITED STATES	COVID-19, Respiratory failure	80.00	Male	Liver transplant; Hepatic cirrhosis(C); Cardiomyopathy(C); Atrial fibrillation(C); Chronic kidney disease(C)	TACROLIMUS	This literature-non-study case was reported in a literature article and describes the occurrence of RESPIRATORY FAILURE (Respiratory failure) and COVID-19 (COVID-19) in an 80-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. LITERATURE REFERENCE: John BV, Deng Y, Khakoo NS, Taddei TH, Kaplan DE, Dahman B. Coronavirus disease 2019 vaccination is associated with reduced severe acute respiratory syndrome coronavirus 2 infection and death in liver transplant recipients. Gastroenterology. 2022;162(2):645-7 The patient's past medical history included Liver transplant. Concurrent medical conditions included Cirrhosis liver (compensated graft cirrhosis), Cardiomyopathy (non ischemic cardiomyopathy), Atrial fibrillation and Chronic kidney disease. Concomitant products included TACROLIMUS for Liver transplant. On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced RESPIRATORY FAILURE (Respiratory failure) (seriousness criteria death and medically significant) and COVID-19 (COVID-19) (seriousness criterion death). The reported cause of death was Respiratory failure and covid-19. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Of the 2 postvaccination COVID-19 deaths, the first was an 80-year-old man who was 9 years post-transplant on tacrolimus, with compensated graft cirrhosis, nonischemic cardiomyopathy, atrial fibrillation, and chronic kidney disease. Patient developed COVID-19 18 days after the second dose of mRNA-1273 vaccine. This patient required mechanical ventilation, pressors, and dialysis and died from respiratory failure.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							Company Comment: This is a literature case concerning a death of an 80-year-old male patient with medical history of liver transplant, Cirrhosis liver (compensated graft cirrhosis), Cardiomyopathy (non ischemic cardiomyopathy), Atrial fibrillation and Chronic kidney disease, on tacrolimus therapy, who experienced the fatal unexpected AESI of COVID-19 and fatal serious unexpected event of respiratory failure. The events occurred 18 days after the second dose of the mRNA-1273 vaccine. As reported, the patient developed COVID-19 18 days after the second dose of mRNA-1273 vaccine. The administration date of first dose was not provided. Patient required mechanical ventilation, pressors, and dialysis and died from respiratory failure. Based on the current available information, the mRNA-1273 does not contain a virus capable of causing COVID-19 infection after vaccination. Hence, considering that respiratory failure was likely caused by COVID 19 causality for event is assessed as not related per Company. Above mentioned patient's medical history and advanced age might have contributed to fatal outcome. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. This case was linked to [redacted] (Patient Link). Most recent FOLLOW-UP information incorporated above includes: On 03-Feb-2022: Follow up received by safety 03-Feb-2022 has Email with FTA received from SARA team and contains significant information: Medical history, reporter information, Authors, concomitant medication and non drug treatment for COVID-19.	
[redacted]	UNITED STATES	COVID-19 pneumonia, Respiratory failure	82.00	Male	Liver transplant; Coronary artery disease(C); Diabetes mellitus(C); Chronic kidney disease(C)	TACROLIMUS	This literature-non-study case was reported in a literature article and describes the occurrence of RESPIRATORY FAILURE (respiratory failure) and COVID-19 PNEUMONIA (COVID-19 pneumonia) in an 82-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. LITERATURE REFERENCE: JOHN BV, DENG Y, KHAKOO NS, TADDEI TH, KAPLAN DE, DAHMAN B. Coronavirus disease 2019 vaccination Is associated with reduced severe acute respiratory syndrome coronavirus 2 infection and death in liver transplant recipients. Gastroenterol. 2022;162(2):645-7 The patient's past medical history included Liver transplant (Patient was 8 years post-transplant on single-agent tacrolimus). Concurrent medical conditions included Coronary artery disease, Diabetes mellitus and Chronic kidney disease. Concomitant products included TACROLIMUS for Immunosuppression. On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							changed to 1 dosage form. On an unknown date, the patient experienced RESPIRATORY FAILURE (respiratory failure) (seriousness criteria death and medically significant) and COVID-19 PNEUMONIA (COVID-19 pneumonia) (seriousness criteria death and medically significant). The reported cause of death was Respiratory failure and COVID-19 pneumonia. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter considered RESPIRATORY FAILURE (respiratory failure) and COVID-19 PNEUMONIA (COVID-19 pneumonia) to be related. Company comment: This is a literature case concerning an 82-year-old male patient with medical history of liver transplant, coronary artery disease, diabetes mellitus and chronic kidney disease, who experienced the serious unexpected AESI of COVID-19 pneumonia and serious unexpected fatal event of respiratory failure. The events occurred 10 days after the second dose of the mRNA-1273 vaccine. Based on the current available information, the mRNA-1273 vaccine does not contain a virus capable of causing COVID-19 infection after vaccination, therefore, the causality for COVID-19 pneumonia is not applicable, while the causality for the event respiratory failure was assessed as related. The rechallenge was not applicable due to the events outcome. The patient's advanced age, underlying medical history and immunosuppressive therapy remain a confounder for the development of COVID-19 pneumonia and subsequent respiratory failure. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. This case was linked to [redacted] (Patient Link). Most recent FOLLOW-UP information incorporated above includes: On 03-Feb-2022: Follow-up received by safety on 03-Feb-2022 included an Email with FTA received from SARA team includes significant information. Literature Information, Relevant history, Concomitant medication were updated.	
[redacted]	FRANCE	Vaccination failure	76.00	Male	Sleep apnoea syndrome(C); Renal transplant; Gout(C); Deafness bilateral(C); Deep vein thrombosis(C); Myocardial ischaemia(C); Dyslipidaemia(C); Hypertension(C); Coronary artery bypass; Optic ischaemic neuropathy(C);	0	This case was initially received via European Medicines Agency (Reference number: [redacted] on 01-Feb-2022. The most recent information was received on 24-Mar-2022 and was forwarded to Moderna on 24-Mar-2022. This regulatory authority case was reported by a physician and describes the occurrence of VACCINATION FAILURE (Vaccination failure) in a 76-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 300042722 & UNK and 300042722 & UNK) for COVID-19 vaccination. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for Revaccination with different COVID-19 vaccine.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
					Atrioventricular block complete(C)		The patient's past medical history included Renal transplant on 21-Apr-2021 and Aortocoronary bypass. Concurrent medical conditions included Sleep apnoea syndromes, Gout, Deafness bilateral, Venous thrombosis deep limb, Ischaemic heart disease, Dyslipidaemia, Hypertension arterial, Anterior ischaemic optic neuropathy in November 2021 and Atrioventricular block third degree. On 12-Feb-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 3 dosage form. On 21-May-2021, received dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 3 dosage form. On 16-Dec-2021, the patient received dose of TOZINAMERAN (COMIRNATY) (Intramuscular) 1 dosage form. On 28-Dec-2021, after starting mRNA-1273 (Spikevax), the patient experienced VACCINATION FAILURE (Vaccination failure) (seriousness criterion death). The patient died on 22-Jan-2022. The reported cause of death was pneumopathie covid-19. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. Dosage text was reported as 1 DF x3 total D1+D2+D3. No treatment information was provided. Company Comment: This regulatory authority case concerns a 76-year-old male patient with no relevant medical history reported, who experienced the fatal unexpected serious event of Vaccination failure which occurred 221 days after the administration of a dose of the mRNA-1273 vaccine and 12 days after the administration of Co-suspect product (non-company product) TOZINAMERAN (COMIRNATY). The patient died approximately 8 months after vaccination with mRNA-1273 and 37 days after the administration of Co-suspect product (non-company product) TOZINAMERAN (COMIRNATY). The reported cause of death was COVID-19 pneumonia. It is unknown if an autopsy was performed. The patient received the second dose 98 days after the first dose, which is not in accordance with the recommended vaccine interval. The patient was noted to have received a different brand of covid-19 vaccine from TOZINAMERAN (COMIRNATY) 6 months 25 days after vaccination with mRNA1273 (Interchange of vaccine products). Patients elderly age could be confounding. The benefit-risk relationship of mRNA-1273 is not affected by this report. The events were assessed as serious as per Regulatory Authority´s report. Most recent FOLLOW-UP information incorporated above includes:	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							On 24-Mar-2022: Follow-up information received included added death date (22-JAN-2022) and cause of death (COVID-19 pneumonitis), event start date corrected from 21-Dec-2021 to 28-Dec-2021, event outcome updated from NOT RECOVERED/NOT RESOLVED to FATAL and seriousness criterion updated from HOSPITALIZATION to DEATH.	
[redacted]	SINGAPORE	Coronary artery stenosis	53.00	Male	Congenital coronary artery malformation(C)	0	This literature-non-study case was reported in a literature article and describes the occurrence of CORONARY ARTERY STENOSIS (Right coronary artery anomalous origin with atherosclerotic ostial stenosis) in a 53-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination. LITERATURE REFERENCE: Yeo A, Kuek B, Lau M, Tan SR, Chan S. Post COVID-19 vaccine deaths - Singapore's early experience. Forensic Sci Int. 2022;332:111199 Concurrent medical conditions included Coronary artery anomaly, congenital. On an unknown date, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. In 2021, after starting mRNA-1273 (COVID 19 Vaccine Moderna), the patient experienced CORONARY ARTERY STENOSIS (Right coronary artery anomalous origin with atherosclerotic ostial stenosis) (seriousness criteria death and hospitalization). The patient died in 2021. The reported cause of death was right coronary artery anomalous origin with atherosclerotic ostial stenosis. An autopsy was performed. Related DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood immunoglobulin E: 279 iu/ml 279 IU/mL. On an unknown date, C-reactive protein: 17.3 mg/l 17.3 mg/L. On an unknown date, Tryptase: 9.1 ug/l 9.1 ug/L. For mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown), the reporter did not provide any causality assessments. No concomitant and treatment medications reported. The patient did not have signs of anaphylaxis and no histological features. It was reported that this study has shown no definite causative relationship between the mRNA vaccination and deaths of individuals who died or collapsed within 72 h after receiving the mRNA COVID-19 vaccination with regards to anaphylactic reactions, myocarditis and pericarditis, and thrombotic complications.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							Company comment: This is a literature case that concerns a 53-year-old male patient with relevant medical history of Coronary artery anomaly, congenital who experienced serious unexpected event of Coronary artery stenosis and subsequently died. The patient died within two days after the second dose of mRNA-1273. The reported cause of death was Right coronary artery anomalous origin with atherosclerotic ostial stenosis. An autopsy was performed but no results were provided. Causality is confounded with patient's reported medical history. Due to nature of the event, the event is unlikely related to the Company product. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. This case was linked to [redacted] (Patient Link). Most recent FOLLOW-UP information incorporated above includes: On 03-Feb-2022: Follow up received by safety 03-Feb-2022 included an Email with FTA received from SARA team and contain any new information. Lab data were Added	
[redacted]	FRANCE	Haemorrhagic stroke	79.00	Male	Myalgia(H); Cerebrovascular accident(H); Hypertension(H); Ex-tobacco user(H); Dyslipidaemia(H); Arrhythmia(H)	ASPIRINETAS; RAMIPRIL; VAXZEVRIA	This case was received via European Medicines Agency on 02-Feb-2022 and was forwarded to Moderna on 02-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of HAEMORRHAGIC STROKE (Hemorrhagic stroke of cerebral barter) in a 79-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 006G21A) for COVID-19 vaccination. The patient's past medical history included Myalgia since 29-Oct-2021, CVA (ischemic), Hypertension arterial (balanced according to the attending physician but noted as no followed by the patient) since an unknown date, Ex-smoker (weaned in 2020), Dyslipidaemia since an unknown date and Arrhythmia (with MP laying) since 2020. Concomitant products included COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) from 30-Mar-2021 to 22-Jun-2021 for COVID-19 immunisation, RAMIPRIL for Hypertension arterial, ACETYLSALICYLIC ACID (ASPIRINETAS) for Implantable cardiac monitor insertion. On 13-Dec-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced HAEMORRHAGIC STROKE (Hemorrhagic stroke of cerebral barter) (seriousness criterion death). The patient died on 04-Jan-2022. The reported cause of death was hemorrhagic stroke of cerebral barter. An autopsy was not performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							On 03-Jan-2022, Computerised tomogram: massive hemorrhagic stroke Massive hemorrhagic stroke. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Coronary heredity was reported. Treatment information was not provided. Company comment: This case concerns a 79-year-old male patient with medical history of CVA, Hypertension, Dyslipidaemia and Arrhythmia, who died due to Hemorrhagic stroke 22 days after the third dose of mRNA-1273. Computerised tomogram one day before death confirmed massive hemorrhagic stroke. An autopsy was not performed. and the reported cause of death was hemorrhagic stroke of cerebral barter. The patient's medical history of CVA, Hypertension, Dyslipidaemia and Arrhythmia in addition to the patient's advanced age, remains a strong confounder. The reporter did not provide causality assessment. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Having in mind that this patient received the COVID-19 VACCINE ASTRAZENECA prior to vaccination with the company product, Interchange of vaccine products should have been considered in this specific case.	
[redacted]	NETHERLANDS	Drug interaction, Myasthenia gravis, Myocardial infarction	47.00	Male	SPIKEVAX; Hypertension(C); Myasthenia gravis(H); COVID-19(H)	0	This case was initially received via European Medicines Agency (Reference number: [redacted] on 01-Feb-2022. The most recent information was received on 17-Mar-2022 and was forwarded to Moderna on 17-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of MYASTHENIA GRAVIS (Unable to swallow; paralysis; his muscle disease went worse), MYOCARDIAL INFARCTION (Multiple heart attacks: multiple minor heart attacks on 06-08) and MYOCARDIAL INFARCTION (Fatal heart attack on 08-08) in a 47-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect products included non-company products DEXAMETHASONE for Myasthenia gravis and PYRIDOSTIGMINE for Myasthenia gravis. The patient's past medical history included Myasthenia gravis and COVID-19 (He was hospitalized because of his muscle disease but was allowed to go home after 1 day.) in 2020. Previously administered products included for Product used for unknown indication: SPIKEVAX on 15-Mar-2021. Past adverse reactions to the above products included No adverse event with SPIKEVAX. Concurrent medical conditions included Hypertension. On 28-Apr-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							On an unknown date, the patient started DEXAMETHASONE (unknown route) at an unspecified dose and PYRIDOSTIGMINE (unknown route) at an unspecified dose. On 06-Aug-2021, the patient experienced MYOCARDIAL INFARCTION (Multiple heart attacks: multiple minor heart attacks on 06-08) (seriousness criterion medically significant). On 08-Aug-2021, the patient experienced MYOCARDIAL INFARCTION (Fatal heart attack on 08-08) (seriousness criterion death). On an unknown date, the patient experienced MYASTHENIA GRAVIS (Unable to swallow; paralysis; his muscle disease went worse) (seriousness criterion medically significant) and DRUG INTERACTION (After the 2nd vaccination, his medication for his muscle disease didn't work well anymore.). The patient died on 08-Aug-2021. The reported cause of death was Heart attack. It is unknown if an autopsy was performed. At the time of death, MYASTHENIA GRAVIS (Unable to swallow; paralysis; his muscle disease went worse), DRUG INTERACTION (After the 2nd vaccination, his medication for his muscle disease didn't work well anymore.) and MYOCARDIAL INFARCTION (Multiple heart attacks: multiple minor heart attacks on 06-08) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, SARS-CoV-2 test positive: positive (Positive) Positive. Concomitant product use was not provided by the reporter. Treatment information was not provided. Because patient describes that the medication for myasthenia gravis of the patient was not working properly anymore, the LLT drug interaction was added and the medication was made a suspect drug. Company comment: This is a fatal, regulatory case concerning a 47-year-old male patient with reported medical history of Myasthenia gravis, COVID-19, and medication history with co-suspect non-company products Dexamethasone and Pyridostigmine for Myasthenia gravis, who experienced the serious fatal unexpected AESI of Myocardial Infarction (reported as fatal heart attack on 08-08), serious (medically significant) unexpected AESI of Myocardial Infarction (reported as multiple heart attacks: multiple minor heart attacks on 06-08), and Myasthenia Gravis. The events occurred approximately 4 months after receiving a dose of mRNA-1273 Vaccine and patient died around the same time. The reported cause of death was Heart attack. It is unknown if an autopsy was performed. The medical history of Myasthenia Gravis and COVID-19 could be considered contributing factors and co-suspect products for Myasthenia Gravis (Dexamethasone and Pyridostigmine) remains confounder	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							as per drug interaction was additionally reported. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 17-Mar-2022: Follow up document received included medical history and sender's comment was added. Event COVID-19 removed in follow up.	
[redacted]	NETHERLANDS	Pneumonia	84.00	Male	Pulmonary embolism(H); Arrhythmia(H); Pneumonia(H); Pulmonary oedema(H); Oesophageal cancer metastatic(C); COMIRNATY; COMIRNATY	LENDORMIN; OXYCODON; B IJZER NUTRIDOSES; ANTICOAGULANT CITRATE DEXTROSE; CODEINE SULPHATE	This case was initially received via European Medicines Agency (Reference number: [redacted] on 01-Feb-2022. The most recent information was received on 14-Feb-2022 and was forwarded to Moderna on 14-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of PNEUMONIA (Then his lungs were full and had pneumonia.) in an 84-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Pulmonary embolism (Family history: False), Arrhythmia (Family history: False), Pneumonia (Family history: False) and Pulmonary edema (Family history: False). Previously administered products included for Product used for unknown indication: COMIRNATY (BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST) on 12-Feb-2021, COMIRNATY (BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST) on 26-Mar-2021. Past adverse reactions to the above products included No adverse reaction with COMIRNATY and COMIRNATY. Concurrent medical conditions included Esophageal cancer metastatic (Family history: False). Concomitant products included BROTIZOLAM (LENDORMIN), OXYCODONE HYDROCHLORIDE (OXYCODON), ASCORBIC ACID, FOLIC ACID, IRON PIDOLATE (B IJZER NUTRIDOSES), ANTICOAGULANT CITRATE DEXTROSE and CODEINE SULFATE (CODEINE SULPHATE) for an unknown indication. On 29-Nov-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 01-Dec-2021, after starting mRNA-1273 (Spikevax), the patient experienced PNEUMONIA (Then his lungs were full and had pneumonia.) (seriousness criterion death). The patient died on 08-Dec-2021. The reported cause of death was longontsteking. An autopsy was not performed. No treatment information was provided. Company Comment: This regulatory case concerns an 84-year-old, male patient with the concurrent condition of metastatic	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							esophageal cancer and past medical history of pulmonary embolism, pulmonary edema and arrhythmia, who experienced the unexpected, fatal event of Pneumonia. The event occurred 2 days after a dose of mRNA-1273 vaccine. It should also be noted that the patient received 2 doses of Tozinameran COVID-19 vaccine approximately 8 months prior to the mRNA-1273 (Interchange of vaccine products). Clinical course leading to demise and treatment details were not provided. The patient died 10 days post-vaccination. Autopsy was not performed in this case. The elderly age of the patient and concurrent metastatic malignancy remain as confounders for the event. Additionally, the elderly age and malignant condition along with history of pulmonary embolism, pulmonary edema and arrhythmia could have contributed to the fatal outcome. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report. Most recent FOLLOW-UP information incorporated above includes: On 14-Feb-2022: Significant follow-up included suspect batch number removed. Concomitant drugs updated.	
[redacted]	GERMANY	Chest pain, Coronary arterial stent insertion, Electrocardiogram abnormal	67.00	Male	Hyperlipidaemia(H); Atrial fibrillation(C); Coronary artery disease(C); Hypertension(C)	0	This case was received via European Medicines Agency (Reference number: [redacted] on 02-Feb-2022 and was forwarded to Moderna on 02-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of CORONARY ARTERIAL STENT INSERTION (Coronary arterial stent insertion), CHEST PAIN (Thorax pain) and ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal) in a 67-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Hyperlipoproteinemia. Concurrent medical conditions included Tachyarrhythmia absoluta, Coronary disease and Arterial hypertension. On 29-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, the patient experienced CORONARY ARTERIAL STENT INSERTION (Coronary arterial stent insertion) (seriousness criteria death, hospitalization and life threatening), CHEST PAIN (Thorax pain) (seriousness criteria death, hospitalization and life threatening) and ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal) (seriousness criteria death, hospitalization and life threatening). The patient died on 29-Dec-2021. The reported cause of death was tu: possible in case of anamnesis and the course of 2nd heart attack. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant Medication use information was not provided by reporter.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							Treatment Medication use information was not provided by reporter. Company comment: This is a regulatory authority case concerning a 67-year-old, male patient with relevant medical history of hyperlipoproteinemia, tachyarrhythmia absoluta, coronary disease and arterial hypertension, who experienced the unexpected serious events of thorax pain, electrocardiogram abnormal and coronary arterial stent insertion. The events thorax pain and electrocardiogram abnormal occurred 11 days before the booster dose of mRNA-1273 vaccine administration while the event coronary arterial stent insertion occurred 6 days before the booster dose of mRNA-1273 vaccine administration which resulted to hospitalization. The outcome of the events thorax pain, electrocardiogram abnormal and coronary arterial stent insertion were fatal. The reported cause of death was possible in case of anamnesis and the course of second heart attack. It is unknown if autopsy was done. The medical history of hyperlipoproteinemia, tachyarrhythmia absoluta, coronary disease and arterial hypertension remain confounders. The benefit-risk relationship of mRNA-I273 vaccine is not affected by this report.	
[redacted]	NETHERLANDS	Cerebral infarction, Dysarthria, Dysphagia, Loss of consciousness, Pneumonia	84.00	Female	Hypersensitivity; Fall(H); Urinary bladder polyp(H); Breast cancer(H); Intermittent claudication(H); Stent placement; PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE; Cataract(H); Urogenital prolapse(H); Hypertension(H); Cognitive disorder(H)	PAROXETIN [PAROXETINE]; METOPROLOL SUCCINAT BETA; ACETYLSALICYLZUUR; CHLOORTALIDON	This case was initially received via European Medicines Agency (Reference number: [redacted] on 01-Feb-2022. The most recent information was received on 24-Jun-2022 and was forwarded to Moderna on 24-Jun-2022. This regulatory authority case was reported by a consumer and describes the occurrence of DYSARTHRIA (could no longer talk and swallow due to infarction), CEREBRAL INFARCTION (Next day cerebral stroke), DYSPHAGIA (could no longer talk and swallow due to infarction), PNEUMONIA (could no longer talk and swallow due to the infarction, developed pneumonia) and CEREBRAL INFARCTION (Another cerebral stroke) in an 84-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 093F21A) for COVID-19 immunisation. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Fall (Fell on her hip, hospitalised for that. Years ago), Urinary bladder polyp (hospitalisation), Breast cancer (hospitalised for breastcancer when she was 50 years old) in 1987, Claudication (treatment: advice to walk, which she did, until she died, targetting 10000 steps per day. In addition acetylsalicylic acid. In 2016 stent placement in her legs) in 2004, Cataract in 2013, Urogenital prolapse (Prolapse uterus and bladder wv, manchesterplastic and back wall plastic) in 2002, Hypertension, Cognitive impairment (mild cognitive impairment) and Stent placement (placing stents in her\ legs (2016)) in 2016. Previously administered products included for Product used for unknown indication: BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST on 26-Feb-2021, BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST on 02-Apr-2021.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							Past adverse reactions to the above products included Confusion with BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST; and No adverse event with BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST. Concurrent medical conditions included Allergy (Rest). Concomitant products included ACETYLSALICYLZUUR for Claudication, METOPROLOL SUCCINATE (METOPROLOL SUCCINAT BETA) and CHLOORTALIDON for Hypertension, PAROXETINE (PAROXETIN [PAROXETINE]) for Seasonal depression. On 12-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 12-Dec-2021, the patient experienced LOSS OF CONSCIOUSNESS (Has had a walk away the same day in the evening). On 13-Dec-2021, after starting mRNA-1273 (Spikevax), the patient experienced CEREBRAL INFARCTION (Next day cerebral stroke) (seriousness criteria death and hospitalization). On 14-Dec-2021, the patient experienced DYSARTHRIA (could no longer talk and swallow due to infarction) (seriousness criteria death and hospitalization), DYSPHAGIA (could no longer talk and swallow due to infarction) (seriousness criteria death and hospitalization), PNEUMONIA (could no longer talk and swallow due to the infarction, developed pneumonia) (seriousness criteria death and hospitalization) and CEREBRAL INFARCTION (Another cerebral stroke) (seriousness criteria death and hospitalization). The patient died on 17-Dec-2021. The reported cause of death was cerebral infarction (primary cause of death) and Pneumonia. An autopsy was not performed. At the time of death, LOSS OF CONSCIOUSNESS (Has had a walk away the same day in the evening) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2021, Blood cholesterol: last measurement of 2021 was 3.6 Annual measurements since 2010 show that total cholesterol was always slightly elevated: between 5.4 and 6.4 (normal =<5), last value in 2021 was 5.9. HDL cholesterol was always tidy: between 1.7 and 2.2. LDL cholesterol, however, usually above the norm (<3= normal) between 2.9-4. Last measurement of 2021 was 3.6. Ratio always neatly below 5. Triglycerides also normal. In 2021, Blood pressure measurement: 140/80 Her blood pressure according to the general practitioner's file 2015:156/81 2016:154/91 2017:163/83 2018:147/81 2019:128/82 2020:130/72 2021:140/80. very adherence to both means to lower blood pressure.. In 2021, Mini mental status examination: 27/30 27/30 test_result_lowest_range : 25 test_result_highest_range : 30. In 2021, Montreal cognitive assessment: 23/30 23/30 test_result_lowest_range : 26 test_result_highest_range : 30.	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							On 13-Dec-2021, Scan: occlusion of the a. vertebralis on the one hand occlusion of the a. vertebralis on the one hand, without evidence of atrial fibrillation. Company Comment: This regulatory case concerns an 84-year-old female patient, with relevant medical history of hypertension, breast cancer, cognitive impairment, claudication of legs s /p stent placement, who experienced the unexpected serious and fatal events of Cerebral infarction (AESI) (reported 2 episodes), Dysarthria, Dysphagia, and Pneumonia. The event Cerebral infarction (next day cerebral stroke) occurred 1 day, and events Cerebral infarction (another cerebral stroke), Dysarthria, Dysphagia, and Pneumonia occurred 2 days, respectively, after receiving the dose of mRNA-1273 vaccine. The events were reported along with the non-serious loss of consciousness that happened same day post vaccination. Scan showed occlusion of the a. vertebralis on the one hand, without evidence of atrial fibrillation. The following tests were done on an unspecified date (units not reported): total cholesterol 5.9, HDL cholesterol between 1.7 and 2.2, LDL cholesterol 3.6, and triglycerides normal, blood pressure 140/80, mini mental status examination 27/30, and montreal cognitive assessment 23/30. Clinical course of hospitalization and treatment details were not reported. The patient died 5 days post vaccination. The causes of death were reported as Cerebral infarction as the primary cause and Pneumonia. Autopsy was not performed. Patient received 2 doses of Tozinameran vaccine at an interval of 35 days with reported adverse event of confusion with the 2nd dose, and the 2nd dose was given 8 months and 10 days prior to the mRNA-1273 vaccine (Interchange of vaccine products noted). The medical history of hypertension, breast cancer, and claudication could be considered as risk factors for the event cerebral infarction. Cognitive impairment as contributory factor for the event dysarthria. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report. Most recent FOLLOW-UP information incorporated above includes: On 24-Jun-2022: Medical history added, Lab tests added, event verbatim updated.	
[redacted]	SPAIN	Chest pain	69.00	Male	Ischaemic cardiomyopathy(H); Chronic kidney disease(H); Alcohol use(H); Hypertension(C); Tobacco abuse(H); Type 2 diabetes mellitus(C); Hyperlipidaemia(C)	0	This case was received via European Medicines Agency (Reference number: [redacted] on 03-Feb-2022 and was forwarded to Moderna on 03-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (Chest pain) in a 69-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3006276, ABY1328 and ABW7197) for COVID-19 vaccination.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							The patient's past medical history included Ischaemic cardiomyopathy in 2005, Renal failure chronic, Alcohol use and Tobacco abuse. Concurrent medical conditions included Hypertension, Type 2 diabetes mellitus and Hyperlipidaemia. On 28-Apr-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 02-Jul-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to .5 milliliter. On 13-Dec-2021, received third dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to .25 milliliter. On an unknown date, after starting mRNA-1273 (Spikevax), the patient experienced CHEST PAIN (Chest pain) (seriousness criterion death). The patient died on 14-Dec-2021. The reported cause of death was cardiorespiratory arrest (10007617). It is unknown if an autopsy was performed. mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on 28-Apr-2021. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. No treatment medications were reported. Company Comment: This regulatory case concerns a 69-year-old, male patient with medical history of medical history of cardiomyopathy in 2005, Renal failure chronic, Alcohol use and Tobacco abuse and Concurrent medical conditions of Hypertension, Type 2 diabetes mellitus and Hyperlipidaemia arterial, who experienced the unexpected serious event of Chest pain, which resulted in a fatal outcome, with death occurring 1 day after the third dose of mRNA-1273 vaccine. The reported cause of death is cardio-respiratory arrest, It is unknown if an autopsy was performed. Inappropriate schedule of product administration was also noted in the case (interval between dose 1 and dose 2 are longer than 35 days), Dose interval is 65 days. Patients medical history of cardiomyopathy in 2005, Renal failure chronic, Alcohol use and Tobacco abuse and Concurrent medical conditions of Hypertension, Type 2 diabetes mellitus and Hyperlipidaemia remains as a confounder. The benefit-risk relationship of mRNA-1273 is not affected by this report. The event was assessed as serious as per Regulatory Authority´s report.	
[redacted]	FRANCE	Sudden death	88.00	Male	Coronary artery disease(H); Diabetes mellitus(C)	0	This case was received via European Medicines Agency (Reference number: [redacted] on 03-Feb-2022 and was forwarded to Moderna on 03-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of SUDDEN DEATH (Sudden death) in an 88-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 007G21A) for COVID-19 vaccination.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							The patient's past medical history included Coronary disease. Concurrent medical conditions included Diabetes. On 12-Jan-2022, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. The patient died on 12-Jan-2022. The reported cause of death was Sudden death. It is unknown if an autopsy was performed. mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on 12-Jan-2022. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medication was not reported. Treatment medication was not reported. Company comment: This case concerns a 88-year-old male patient, with medical history of Coronary disease and diabetes, who experienced the serious, fatal, unexpected event of sudden death. The event happened 3 hours after the first dose of mRNA 1273 COVID-19 Vaccine. No further details were provided. It is unknown if an autopsy was performed. The patient's age and history of coronary disease and diabetes remain as confounders to the event. The benefit-risk relationship of mRNA 1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 03-Feb-2022: Follow-up information received included added medical history and concomitant drugs.	
[redacted]	GERMANY	Sudden death	63.00	Male	Myasthenia gravis(C); AZATHIOPRIN(H)	0	This case was initially received via European Medicines Agency (Reference number: [redacted] on 07-Feb-2022. The most recent information was received on 07-Feb-2022 and was forwarded to Moderna on an unknown date. This regulatory authority case was reported by a physician and describes the occurrence of SUDDEN DEATH (Sudden death unexplained) in a 63-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000128A) for COVID-19 vaccination. Previously administered products included for Product used for unknown indication: Azathiopin. Past adverse reactions to the above products included No adverse event with Azathiopin. Concurrent medical conditions included Myasthenia gravis. On an unknown date, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							No concomitant medication were reported. No treatment information was provided by the reporter. Dosage text was reported as booster vaccination. Company comment: This regulatory authority case concerns a 63-year-old male patient, with Myasthenia gravis, who experienced the serious fatal unexpected event of Sudden death after a dose of mRNA-1273 (reported as booster dose). No information regarding date of vaccination. Cause of death and date of death was not reported. It is unknown if an autopsy was performed. Patient´s mentioned medical history remains a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 07-Feb-2022: Upon query received from business partner, significant correction was performed on 21-MAR-2022. The company comment was updated.	
[redacted]	GERMANY	Cerebral infarction, Cerebrovascular accident, Hemiparesis	80.00	Male	Atrial fibrillation(C); BNT162B2; BNT162B2	0	This case was received via European Medicines Agency (Reference number: [redacted]) on 07-Feb-2022 and was forwarded to Moderna on 07-Feb-2022. This regulatory authority case was reported by a pharmacist and describes the occurrence of CEREBROVASCULAR ACCIDENT (Stroke), HEMIPARESIS (Hemiparesis) and CEREBRAL INFARCTION (Cerebral infarction) in an 80-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 092F21A) for COVID-19 vaccination. Previously administered products included for COVID-19 vaccination: Comirnaty BNT162b2 on 28-Apr-2021 and Comirnaty BNT162b2 on 09-Jun-2021. Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Comirnaty BNT162b2. Concurrent medical conditions included Atrial fibrillation. On 17-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 03-Jan-2022, the patient experienced CEREBROVASCULAR ACCIDENT (Stroke) (seriousness criteria death, hospitalization and life threatening), HEMIPARESIS (Hemiparesis) (seriousness criteria death, hospitalization and life threatening) and CEREBRAL INFARCTION (Cerebral infarction) (seriousness criteria death, hospitalization and life threatening). The patient died on 04-Jan-2022. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant Medication use information was not provided by reporter.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							Treatment Medication use information was not provided by reporter. Company comment: This Fatal Regulatory Authority case concerns a 80-year-old, male patient, with medical history of atrial fibrillation, who experienced the unexpected, serious (death/ life threatening/ hospitalization) and AESI of Cerebrovascular accident and cerebral infarction, among others. The events occurred approximately 27 days after receiving a dose of mRNA-1273 vaccine, considered as the third dose of the patient's COVID-19 vaccination schedule, as he received previously two doses of Comirnaty's COVID-19 vaccine as first and second doses. The patient died the day after the events developed. Cause of death was reported as unknown. Autopsy report is not available. The medical history of atrial fibrillation remains as a confounder. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.	
[redacted]	JAPAN	Cardio-respiratory arrest, Death, Depressed level of consciousness, Pyrexia	53.00	Female	Asthma(C); Rheumatic disorder(H); COMIRNATY; COMIRNATY	0	This case was received via Takeda Pharmaceuticals (Reference number:[redacted] on 07-Feb-2022 and was forwarded to Moderna on 09-Feb-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a (physician), was received via the PMDA (Ref,[redacted]). The patient was confined to a wheelchair.The patient had deformed feet due to rheumatism and had a history of surgery. On 22-Jun-2021, the patient received the 1st dose of SARS-CoV-2 vaccine (coronavirus modified uridine RNA vaccine made by Pfizer). On 13-Jul-2021, the patient received the 2nd dose of SARS-CoV-2 vaccine (coronavirus modified uridine RNA vaccine made by Pfizer). After the vaccination, pyrexia developed. On an unknown date, body temperature before the vaccination: 36 degrees Celsius. On 03-Feb-2022, at 13:30, the patient received the 3rd vaccination with this vaccine. Thereafter, there were no changes in the patient's condition. On 04-Feb-2022, around 11:30, pyrexia of 39.0-39.9 degrees Celsius developed. The patient took acetaminophen. Around 12:00, the patient had somnolence. At 14:45, the patient experienced decreased consciousness and cardio-respiratory arrest. At 16:05, resuscitation was performed, and spontaneous circulation returned. The patient was hospitalized with a respirator. On 05-Feb-2022, at 00:13, the patient died. The outcome of pyrexia, decreased consciousness, and cardiac-respiratory was unknown.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							Follow-up investigation will be made. Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.	
[redacted]	JAPAN	Acidosis, Arthralgia, Cardiac arrest, Listless, Oedema peripheral, Pericarditis, Pleural effusion, Pulmonary congestion	94.00	Female	Diabetes mellitus(C); Chronic kidney disease(C); Cardiac failure chronic(C); Dementia(C); Chronic sinusitis(C); Bronchitis chronic(C); Angina pectoris(C); Hyperuricaemia(C); Constipation(C); Subarachnoid haemorrhage(H); CELECOX(H); KAKKONTOKA SENKYUSHIN'I [CINNAMOMUM CASSIA BARK;CNIDIUM OFFICINALE RHIZOME;EPHE DRA SPP. HERB;GLYCYR RHIZA SPP. ROOT;MAGNOL IA SPP. FLOWER;PAEO NIA LACTIFLORA ROOT;PUERARI A LOBATA ROOT;ZINGIBE R OFFICINALE RHIZOME;ZIZIP HUS JUJUBA FRUIT](H); Spinal operation	CALONAL; TRAZENTA; AMLODIN; LASIX P; ALDACTONE A; FEBURIC; MEMARY; BISOLVON; GASMOTIN SR; YODEL-S	This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted]) on 07-Feb-2022. The most recent information was received on 09-Mar-2022 and was forwarded to Moderna on 17-Mar-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref.[redacted]. On 09-Mar-2022, follow-up information was received from a physician. The vaccine recipient underwent cervical spine surgery in 2007 and had been receiving treatments twice a month continuously after the surgery. On an unspecified date in 2009, the patient had a history of traumatic subarachnoid hemorrhage. On an unspecified date in 2014, the patient had a chronic pulmonary murmur, and CT examination was performed for productive cough, and the patient was diagnosed as chronic bronchitis on imaging examination. As for the underlying heart failure, there was no acute heart failure episode and edema of the lower extremities was being controlled with diuretics. On 09-Jun-2021, the patient received the 1st dose of a novel coronavirus vaccine (product name unknown). There were no subjective symptoms. On 30-Jun-2021, the patient received the 2nd dose of a novel coronavirus vaccine (product name unknown). On 07-Jul-2021, the patient had a medical examination. It was reported that the patient was less talkative and less energetic. In addition, increased edema of the lower extremities was observed. Blood pressure and SpO2 were not different from usual values. On 21-Jul-2021, the patient had the second medical examination. The patient was fine and looked normal. On an unspecified date in Aug-2021, the patient experienced coxalgia in the standing position. The patient took acetaminophen 600 mg/day. From an unspecified date in Dec-2021 to an unspecified date in Jan-2022, the only change in the prescription was reduction in the dosage of acetaminophen to 400 mg/day. On an unknown date, body temperature before vaccination: 36.2 degrees Celsius. On 07-Jan-2022, at 10:00, the patient received the 3rd dose of this vaccine. At the time of the vaccination, the patient did not have physical deconditioning immediately after the vaccination. On 09-Jan-2022, there were no other objective symptoms. On 10-Jan-2022, at 02:30, pericarditis developed. The patient complained of queasy feeling, headache, and heaviness and pain-like symptom in the chest. At 04:00, the patient was complaining of queasy feeling and chest discomfort, without feeling dyspnea. Thereafter, the patient fell asleep. At 10:00, the patient complained of tingling in the chest without queasy feeling. Blood pressure was 122/79 mmHg with pulse of 68 beats/min. The patient had little appetite and only drank fluids. At 13:10, after drinking water, the patient complained of headache and heavy chest and rested in the afternoon. The patient drank water along the way. At 17:45, the patient ate a small amount of dinner. The patient took regular medications after	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							meal. At 18:10, there was no queasy feeling. At 20:10, the patient went to bed. At 22:00, the patient continued to have hiccups and complained of neck pain. Blood pressure was 136/77 mmHg with pulse of 91/min, body temperature of 36.4 degrees Celsius, and SpO2 of 80-84%. At 22:40, the patient vomited a small amount of saliva. At 23:00, the patient complained of body pain. On 11-Jan-2022, until 01:30, the patient repeated supine and sitting positions in bed. There was no vomiting. At 02:30, the facial expression improved a bit. At 05:00, the patient said that there was no body pain, but mild rumbling wheezing was noted in the laryngeal region. Blood pressure was 121/74 mmHg with pulse of 111/min, SpO2 of 80%, and body temperature of 35.6 degrees Celsius. At 07:45, the patient had difficulty eating breakfast on the bed by herself and was assisted in a wheelchair. At 08:10, immediately after the patient was transferred to bed, she did not have focused eyes and ill complexion. When tapping was performed, it was judged that there was vomiting but no respiration or pulse. At 08:15, an ambulance call was made. Cardiopulmonary resuscitation was started using AED. At 08:20, the ambulance team arrived. The initial waveform was cardiac arrest. Laryngeal tube was inserted to secure the route. At 08:37, adrenaline was administered. At 08:41, the 2nd dose of adrenaline was administered. At 08:42, the patient arrived at a hospital. When the patient arrived at the hospital, monitor check confirmed ROSC. JCS: 300. There was no spontaneous breathing. Cardiac ultrasonography showed visual EF was about 40%, and local asynergy was not noted. Thereafter, CPA occurred again within a short period of time. There was no obvious injury on the body surface. Intubation revealed a large amount of pink foamy sputum. Blood gas showed high degree of mixed acidosis, and chest X-ray test showed prominent butterfly shadow. CT scan was performed. Head: there was no obvious hemorrhage. Chest: extensive ground glass opacities to infiltrative opacities were noted predominately in both lung inner layers, and bilateral pleural effusion were noted. There was no abnormal pericardial effusion. There was no aortic aneurysm or enlargement of aortic diameter. Thickened bronchial wall was noted, and airway inflammation was suspected. Abdomen: there was thinning of the spleen and liver. CPR was then performed for 30 minutes, but the heartbeat did not resume without ROSC. The patient's family member consented to discontinuation of CPR. At 09:47, the patient was confirmed dead. The cause of death was heart disorder. No necropsy was performed. There was a finding of pulmonary congestion, and an adverse reaction to this vaccine was suspected. The outcome of less talkative and less energetic was reported as resolved. The outcome of increased edema of the lower extremities, coxalgia, mixed acidosis, pleural effusion, and pulmonary congestion was unknown. The outcome of acute pericarditis and cardio-respiratory arrest was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: Since pericarditis is suspected based on the symptoms and course, the cause of death is related to adverse events. On 07-Jan-2022, the patient received this vaccine, and on 10-Jan-2022, the patient experienced chest symptoms and cardiac failure with a sudden onset of the symptoms, so the onset of	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							adverse events is temporally related to the timing of administration of this vaccine. The onset of adverse events is not related to concomitant drugs. The onset of adverse events is not related to pathological factors of underlying diseases and complications. Three days after the vaccination with this vaccine, the patient experienced chest discomfort and queasy feeling without any previous symptoms. Throughout the course of the symptoms, diaphragmatic irritation symptoms such as hiccup, neck pain, and queasy feeling, were main, and hypoxia was ongoing without significant change in blood pressure. Therefore, it is considered that the patient experienced acute pericarditis rather than myocarditis. Follow-up received on 09-MAR-2022 Updated: Patient Information, Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.	
[redacted]	GERMANY	Death, Dehydration	82.00	Male	Cardiac failure(C)	0	This case was received via European Medicines Agency (Reference number: [redacted] on 08-Feb-2022 and was forwarded to Moderna on 08-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (Cause of death unknown) and DEHYDRATION (Nausea, malaise, apathy, lack of response to speech. Initial diagnosis: dehydration) in an 82-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000117A) for COVID-19 vaccination. Patient's information on risk factors or pre-existing diseases included heart failure. Concurrent medical conditions included Cardiac insufficiency. On 05-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 3 dosage form. On 05-Jan-2022, the patient experienced DEHYDRATION (Nausea, malaise, apathy, lack of response to speech. Initial diagnosis: dehydration) (seriousness criterion hospitalization). The patient died on 06-Jan-2022. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, DEHYDRATION (Nausea, malaise, apathy, lack of response to speech. Initial diagnosis: dehydration) had not resolved. No concomitant medications were reported. Patient had vaccination in morning. In the evening RTW call was made for nausea, malaise, apathy, lack of response to speech. Initial diagnosis of dehydration was made. Infusion for compensation was done. Patient was admitted to hospital in normal ward. Patient deceased in the morning, cause of death was unclear. Switching on the Kripo showed that there was no indication of third-party fault and the cause of death was	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							unresolved. Several times it was pointed out vaccination without reaction. Company Comment - This regulatory authority case concerns a 82 year old male patient with medical history of heart failure and cardiac insufficiency, who experienced the serious unexpected events of death and dehydration. The events occurred on the same day after a dose of mRNA-1273 vaccine. The outcome was fatal with death occurring 1 day after the onset of events. The reported cause of death was unknown. Patient's medical history of heart failure and cardiac insufficiency remains a confounder. The rechallenge was not applicable. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.	
[redacted]	ITALY	Acute kidney injury, Cardiomegaly, Generalised oedema, Shock	77.00	Female	Cholelithiasis(H); Acute myeloid leukaemia(H); Type 2 diabetes mellitus(C); Hypothyroidism(C); Chronic kidney disease(C); Cardiac failure(C); Humerus fracture(H); Cerebrovascular accident(H); COMIRNATY; COMIRNATY	TRITTICO; LASIX P; TORVAST; FLUVION; CETIRIZINE; COUMADIN; LANSOX; ZAROXOLYN; CALCITRIOL; ZOLOFT; BISOPROLOL; ABASAGLAR; EUTIROX	This case was initially received via European Medicines Agency (Reference number: [redacted] on 07-Feb-2022. The most recent information was received on 07-Mar-2022 and was forwarded to Moderna on 07-Mar-2022. This regulatory authority case was reported by a physician and describes the occurrence of SHOCK (acute on chronic renal failure requiring dialysis, shock, anasarcatic congestive state, cardiomegaly), ACUTE KIDNEY INJURY (acute on chronic renal failure requiring dialysis, shock, anasarcatic congestive state, cardiomegaly), CARDIOMEGALY (acute on chronic renal failure requiring dialysis, shock, anasarcatic congestive state, cardiomegaly) and GENERALISED OEDEMA (acute on chronic renal failure requiring dialysis, shock, anasarcatic congestive state, cardiomegaly) in a 77-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3005887) for COVID-19 vaccination. The patient's past medical history included Gallbladder stones, Acute myeloid leukaemia on 01-Jan-1993, Humerus fracture and Stroke on 01-Jul-2017. Previously administered products included for SARS-CoV-2 immunisation: COMIRNATY (COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03)) on 25-Mar-2021 and COMIRNATY (COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03)) on 14-Apr-2021. Past adverse reactions to the above products included No adverse event with COMIRNATY and COMIRNATY. Concurrent medical conditions included Type 2 diabetes mellitus, Hypothyroidism on 01-Jan-1996, Chronic renal insufficiency (stage IV) and Decompensation cardiac (heart disease) on 01-Jan-2021. Concomitant products included LEVOTHYROXINE SODIUM (EUTIROX) for Hypothyroidism, TRAZODONE HYDROCHLORIDE (TRITTICO), FUROSEMIDE (LASIX P), ATORVASTATIN CALCIUM (TORVAST), FLUPHENAZINE DECANOATE (FLUVION), CETIRIZINE, WARFARIN SODIUM (COUMADIN), LANSOPRAZOLE (LANSOX), METOLAZONE (ZAROXOLYN), CALCITRIOL, SERTRALINE HYDROCHLORIDE (ZOLOFT), BISOPROLOL and INSULIN GLARGINE (ABASAGLAR) for an unknown indication.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							On 15-Nov-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On 16-Jan-2022, the patient experienced SHOCK (acute on chronic renal failure requiring dialysis, shock, anasarcatic congestive state, cardiomegaly) (seriousness criterion death), ACUTE KIDNEY INJURY (acute on chronic renal failure requiring dialysis, shock, anasarcatic congestive state, cardiomegaly) (seriousness criterion death), CARDIOMEGALY (acute on chronic renal failure requiring dialysis, shock, anasarcatic congestive state, cardiomegaly) (seriousness criterion death) and GENERALISED OEDEMA (acute on chronic renal failure requiring dialysis, shock, anasarcatic congestive state, cardiomegaly) (seriousness criterion death). The patient died on 28-Jan-2022. The reported cause of death was Shock cardiogenic. An autopsy was not performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 16-Jan-2022, Abdominal X-ray: negative (Negative) Negative. On 16-Jan-2022, Blood gases: negative (Negative) Negative. On 16-Jan-2022, Blood test: negative (Negative) Negative. On 16-Jan-2022, Chest X-ray: negative (Negative) Negative. On 16-Jan-2022, Specialist consultation: negative (Negative) Negative. On 16-Jan-2022, Ultrasound scan: negative (Negative) Negative. On 17-Jan-2022, Echocardiogram: negative (Negative) Negative. On 17-Jan-2022, SARS-CoV-2 test: negative (Negative) Negative. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. It was reported that on 28-Jan-2022, the patient died from irreversible cardiogenic shock. Treatment mediations were not reported. Senders comment: Clinical report provided by the reporter was attached. On 28 Jan 2022 the patient died of irreversible cardiogenic shock. Company comment: This regulatory authority case concerns a 77-year-old female patient, with relevant medical history of stroke in 2017 and concurrent conditions type 2 diabetes mellitus, cardiac decompensation and chronic renal insufficiency, who experienced the serious, unexpected fatal events of shock, generalized edema, cardiomegaly and acute kidney injury (AESI). The events occurred approximately 2 months after the 3rd dose of mRNA 1273. Additionally, there was an interchange of vaccine products	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							as the patient was previously vaccinated with 2 doses of Comirnaty. The patient passed away12 days after the onset due to irreversible cardiogenic shock. It is unknown whether autopsy was performed. The patient's advanced age, history of stroke and multiple comorbidities (type 2 diabetes mellitus, heart disease and chronic renal insufficiency) remain confounders for the events and the fatal outcome. Additionally, concomitant furosemide is a possible confounder for shock and AKI, fluphenazine for AKI and metolazone for renal insufficiency. The benefit-risk relationship of mRNA 1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 07-Mar-2022: Follow-up Received : Lab test result (Abdominal X-ray NOS, Arterial blood gases, Blood test NOS, CXR, Echocardiography, COVID-19 PCR test, Nephrologist consultation, Echography) updated.	
[redacted]	TAIWAN, PROVINCE OF CHINA	Cardiac arrest	71.00	Female	Diabetes mellitus(C); Hypertension(C)	0	This regulatory authority case was reported by an other health care professional and describes the occurrence of CARDIAC ARREST (At 05:00 on January 18, 2022, unexplained cardiac arrest occurred.) in a 71-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Diabetes (Information from patient and family) and Blood pressure high (Information from patient and family). On 17-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) .25 milliliter. On 18-Jan-2022, the patient experienced CARDIAC ARREST (At 05:00 on January 18, 2022, unexplained cardiac arrest occurred.) (seriousness criterion death). It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood creatine phosphokinase MB: 8.3 8.3 ng/mL. On an unknown date, Blood potassium: 5.4 5.4mEq/L. On an unknown date, Troponin T: 427.0 427.0ng/L. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were provided. On 17-Jan-2022 at 10:42 the patient received the third dose of Moderna vaccine, Patient general appearance was fair and consciousness was clear. She had no evidence of pain. On 18-Jan-2022 at 05:07, she was sent to ER by EMT (E1V1M1). Her granddaughter reported that, she had chest discomfort last night. Cardiac arrest was found by the EMT at the scene. She was given	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							CPCR with Epinephrine 1mg/ml/amp IV every 3 min. On 18-Jan-2022 at 05:39, there was CPCR failure and at 5:44 there was no spontaneous circulation. Issued a medical certificate for diagnosis: cardiac arrest before admission to hospital. The follow-up care was as follows: On 21-Jan-2022, the patient was called for three consecutive days but no one answered. It was asked to continued follow up with the patient. On 22-Jan-2022 at 10:00/14:54 no one answered the phone. WWID was reported as [redacted] Company comment This regulatory authority case concerns a 71-year-old female patient, with medical history of Diabetes and Blood pressure high, who experienced the unexpected serious (death) fatal event of CARDIAC ARREST, which occurred on the following day of the third dose of mRNA-1273. Cardiac arrest was found by the EMT at the scene. She was given CPCR with Epinephrine. There was CPCR failure. Issued a medical certificate for diagnosis: cardiac arrest before admission to hospital. The mentioned medical history remains as a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Non-Significant Follow up received, updated event verbatim.	
[redacted]	TAIWAN, PROVINCE OF CHINA	Syncope	61.00	Female	Dialysis; Diabetes mellitus(C); Hypertension(C); ASTRAZENECA COVID-19 VACCINE; ASTRAZENECA COVID-19 VACCINE	0	This regulatory authority case was reported by an other health care professional and describes the occurrence of SYNCOPE (Faint) in a 61-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 072F21A_1110129-CDC) for COVID-19 vaccination. The patient's past medical history included Renal dialysis. Previously administered products included for Product used for unknown indication: ASTRAZENECA COVID-19 VACCINE (first dose) on 17-Jun-2021 and ASTRAZENECA COVID-19 VACCINE (second dose) on 23-Sep-2021. Past adverse reactions to the above products included No adverse event with ASTRAZENECA COVID-19 VACCINE and ASTRAZENECA COVID-19 VACCINE. Concurrent medical conditions included Diabetes and Hypertension. On 18-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 20-Jan-2022, the patient experienced SYNCOPE (Faint) (seriousness criterion death). The patient died on 20-Jan-2022. The reported cause of death was Faint. An autopsy was performed. The autopsy-determined cause of death was Atherosclerotic cardiovascular disease and end-stage renal disease.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, SARS-CoV-2 test: result pending Result pending. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. WWID was reported as [redacted] No concomitant medication was provided. On 19-Jan-2022, the patient said to her neighbor that she had symptoms of discomfort such as limb weakness, vomiting and diarrhea. On 20-Jan-2022, her neighbor found that she had not gone out, then her neighbor entered her room to visit the patient with the key given by the deceased. The neighbor found that the patient fell down on the ground, then the neighbor dialed phone. When the relevant personnel arrived at the site and assessed that the patient had died obviously, the patient was not sent to the hospital. Preliminary study and judgment report of forensic anatomy on 24-Jan-2022, showed atherosclerotic cardiovascular disease (90percentage of the three major coronary arteries were blocked), and end-stage renal disease (renal dialysis). Judicial autopsy was performed on 24-Jan-2022. No treatment medication was provided. Company comment: This regulatory authority follow up case concerns a 61 year old female patient with relevant medical history of renal dialysis, diabetes and hypertension, who met with the unexpected fatal (seriousness criterion-death) event of Syncope, about 2 days after receiving the third dose with mRNA-1273 vaccine in the COVID-19 vaccination series. The event had a fatal outcome with death occurring on the 3rd day of vaccine administration. Patient reported of symptoms of discomfort such as limb weakness, vomiting and diarrhea on the second day of vaccination. On the third day, she fell down on the ground and was found by her neighbor. The rescue team was called but could not revive her. The patient received the previous two doses with AstraZeneca Covid-19 vaccine with no reported adverse events, the last dose being given about 3 months and 26 days prior to mRNA-1273 vaccine. Interchange of vaccine products was noted. The autopsy report revealed the cause of death as Syncope along with Atherosclerotic cardiovascular disease and End stage renal disease. Medical history of renal dialysis, diabetes and hypertension could be confounding for the event Syncope. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event's seriousness retained as per Regulatory Authority reporting. Most recent FOLLOW-UP information incorporated above includes:	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							On 25-Apr-2022: Significant follow-up appended, Patient id, history, cause of death, autopsy result, lab test, event verbatim, and I-narrative updated.	
[redacted]	TAIWAN, PROVINCE OF CHINA	Syncope	63.00	Female	End stage renal disease(C); Type 2 diabetes mellitus(C); Hypertension(C); Viral hepatitis carrier(C); Haemodialysis; ASTRAZENECA COVID-19 VACCINE; ASTRAZENECA COVID-19 VACCINE	0	This regulatory authority case was reported by an other health care professional and describes the occurrence of SYNCOPE (Faint) in a 63-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 050F21A_1110124-CDC) for COVID-19 vaccination. The patient's past medical history included Haemodialysis. Previously administered products included for COVID-19 vaccination: AZ vaccine (vaccinated in Antai Hospital) on 17-Jun-2021 and AZ vaccine (vaccinated in Antai Hospital) on 23-Sep-2021. Past adverse reactions to the above products included No adverse event with AZ vaccine and AZ vaccine. Concurrent medical conditions included End stage renal disease (ESRD), Type 2 diabetes mellitus, Hypertension and Hepatitis B carrier. On 13-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) .25 milliliter. On 14-Jan-2022, the patient experienced SYNCOPE (Faint) (seriousness criterion death). The patient was treated with NORMAL SALINE (intravenous) at a dose of 500 ml IV ST; NAHCO3 (intravenous) at a dose of 1 dosage form, 6 Amp IV ST; EPINEPHRINE (intravenous) at a dose of 1 dosage form, 1 amp IV every 3 minutes and EPINEPHRINE (intravenous) on 15-Jan-2022 at a dose of 1 dosage form, 10 Amp. It is unknown if an autopsy was performed. Not Provided DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 15-Jan-2022, SARS-CoV-2 test: negative (Negative) Negative. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were provided by the reporter. It was reported that the family member of the patient said that the patient had a poor appetite and general discomfort that day. After returning home in the evening, it was found that the patient fell down on the ground in the room and was unconscious. Phone number 119 was urgently called, and CPCR was performed. EMT personnel checked after arriving and found that the patient had no spontaneous pulse or breathing. After the emergency doctor diagnosed, CPCR was given continuously, an endotracheal tube respirator was placed. By 01/15 00:29, a total number of 10amp epinephrine was given, but the patient still had no spontaneous pulse. After the doctor explained the condition, the family members accepted it, declared the first aid invalid, and sent the patient home by ambulance at 01:40.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							The follow-up care is as follows 01/18/2022 01/18 Summary of epidemic situation survey of death cases after receiving COVID-19 vaccine in Xinyuan Township, Pingtung County. 01/13 The patient experienced general malaise, poor appetite, and was found lying unconscious at home in the evening. At 23:56, the family dialed 119 and sent her to Antai Community Hospital. The doctor continued to give CPCR, and put in endotracheal tube respirator, N/S 500ml IV ST, NaHCO3 6amp ST IV and epinephrine 1 amp IV every 3 minutes and it was declared that the first aid was ineffective. On 15-JAN-2022, Antai Hospital reported the adverse vaccine event, and the family member of the patient was followed up for the intention for judicial examination. CC: This is a fatal case with interchange of vaccine product reported by the regulatory authority concerning a 63-year-old, female patient with medical history of hepatitis B, hypertension, type 2 diabetes and, end stage renal disease, who experienced the unexpected fatal event of syncope. One day after the administration of the booster dose of mRNA-1273 vaccine, the patient experienced general malaise, poor appetite, and was found lying unconscious at home. Patient was treated with cardiopulmonary resuscitation, IV epinephrine and fluids, unsuccessfully. Underlying conditions are confounders. Patient has had received 2 doses of COVID-19 Vaccine from another pharmaceutical company (AstraZeneca) approximately 4 months prior to mRNA-1273 vaccine. Cause of death was no further specified. It is unknown if autopsy was performed. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Non significant follow up received.	
[redacted]	JAPAN	Acute myocardial infarction, Cardio-respiratory arrest, Feeling abnormal, Malaise	86.00	Male	Hypertension(C); Diabetes mellitus(C); COMIRNATY; COMIRNATY; Eczema(C); Dementia(C); Insomnia(C); Cerebral infarction(C); Cardiac failure chronic(C); Back pain(C); Femoral neck fracture(H); Spinal compression fracture(H)	NEXIUM EBB; RUPAFIN; MEMANTINE HYDROCHLORIDE OD; SERTRALINE; BAYASPIRIN; ZOLPIDEM TARTRATE; CELECOXIB; AMLODIPINE	This spontaneous case was reported by a physician and describes the occurrence of ACUTE MYOCARDIAL INFARCTION (Painless acute myocardial infarction) and CARDIO-RESPIRATORY ARREST (Cardio-respiratory arrest) in an 86-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (batch no. 3005786) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Femoral neck fracture (Left femoral neck fracture) and Lumbar spine compression fracture (Lumbar vertebral compression fracture L4) on 12-Nov-2019. Previously administered products included for Product used for unknown indication: Comirnaty on 18-May-2021 and Comirnaty on 14-Jun-2021. Past adverse reactions to the above products included No adverse event with Comirnaty and Comirnaty. Concurrent medical conditions included Hypertension, Diabetes mellitus, Chronic eczema, Dementia, Insomnia, Late effects of cerebral infarction, Cardiac failure chronic and Low back pain.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							Concomitant products included ESOMEPRAZOLE MAGNESIUM (NEXIUM EBB), RUPATADINE FUMARATE (RUPAFIN), MEMANTINE HYDROCHLORIDE (MEMANTINE HYDROCHLORIDE OD), SERTRALINE, ACETYLSALICYLIC ACID (BAYASPIRIN), ZOLPIDEM TARTRATE, CELECOXIB and AMLODIPINE for an unknown indication. On 07-Feb-2022, the patient received third dose of mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (Intramuscular) .25 milliliter. On 08-Feb-2022, the patient experienced ACUTE MYOCARDIAL INFARCTION (Painless acute myocardial infarction) (seriousness criteria death and medically significant), CARDIO-RESPIRATORY ARREST (Cardio-respiratory arrest) (seriousness criteria death and medically significant), FEELING ABNORMAL (Strange feeling) and MALAISE (Malaise in the body). The patient died on 08-Feb-2022. The reported cause of death was painless acute myocardial infarction and Cardio-respiratory arrest. An autopsy was not performed. At the time of death, FEELING ABNORMAL (Strange feeling) and MALAISE (Malaise in the body) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 28-Jun-2021, Alanine aminotransferase (10-42): 11 (normal) 11 international unit per litre. On 28-Jun-2021, Aspartate aminotransferase (13-30): 17 (normal) 17 international unit per litre. On 28-Jun-2021, Blood bilirubin (0.4-1.5): 0.5 (normal) 0.5 milligram per decilitre. On 28-Jun-2021, Blood calcium (8.8-10.1): 8.9 (normal) 8.9 milligram per decilitre. On 28-Jun-2021, Blood cholesterol (142-248): 209 (normal) 209 milligram per decilitre. On 28-Jun-2021, Blood creatinine (0.65-1.07): 1.18 (High) 1.18 milligram per decilitre. On 28-Jun-2021, Blood glucose (73-109): 103 (normal) 103 milligram per decilitre. On 28-Jun-2021, Blood lactate dehydrogenase (124-222): 162 (normal) 162 international unit per litre. On 28-Jun-2021, Blood potassium (3.6-4.8): 4.0 (normal) 4.0 millimole per litre. On 28-Jun-2021, Blood sodium (138-145): 143 (normal) 143 millimole per litre. On 28-Jun-2021, Blood triglycerides (40-149): 157 (High) 157 milligram per decilitre. On 28-Jun-2021, Blood urea (8-20): 24 (High) 24 milligram per decilitre. On 28-Jun-2021, Blood uric acid (3.7-7.8): 8.3 (High) 8.3 milligram per decilitre. On 28-Jun-2021, Eosinophil count (Unknown-6.0): 7.6 (High) 7.6 % percent.	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							On 28-Jun-2021, Gamma-glutamyltransferase (13-64): 25 (normal) 25 international unit per litre. On 28-Jun-2021, Glycosylated haemoglobin (4.9-6.0): 6.6 (High) 6.6 % percent. On 28-Jun-2021, High density lipoprotein (40-90): 33 (normal) 33 milligram per decilitre. On 28-Jun-2021, LDL/HDL ratio: 5.3 5.3. On 28-Jun-2021, Low density lipoprotein (65-139): 152 (High) 152 milligram per decilitre. On 28-Jun-2021, Mean cell haemoglobin concentration (31.7-35.3): 31.5 (normal) 31.5 gram per decilitre. On 28-Jun-2021, N-terminal prohormone brain natriuretic peptide (Unknown-125): 164 (High) 164 picogram per millilitre. On 28-Jun-2021, White blood cell count: 7800 7800. On 07-Feb-2022, Blood pressure measurement: 120/82 120/82. On 07-Feb-2022, Body temperature: 36.2 36.2 degree Celsius. On 07-Feb-2022, Heart rate: 96 96. On 08-Feb-2022, Breath sounds: no sound was heard No sound was heard. On 08-Feb-2022, Carotid pulse: no pulse was felt No pulse was felt. On 08-Feb-2022, Heart sounds: no sound was heard No sound was heard. On 08-Feb-2022, Pupillary light reflex tests: disappeared Disappeared. On an unknown date, Body temperature: 36.2 36.2 degree Celsius. For mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (Intramuscular), the reporter considered ACUTE MYOCARDIAL INFARCTION (Painless acute myocardial infarction), CARDIO-RESPIRATORY ARREST (Cardio-respiratory arrest), FEELING ABNORMAL (Strange feeling) and MALAISE (Malaise in the body) to be possibly related. Company comment: This case concerns a 86-year-old male patient with hypertension and diabetes mellitus, who experienced the fatal serious unexpected events of acute myocardial infarction and cardio-respiratory arrest, on the next following day after receiving the third dose of mRNA-1273. It was reported patient appeared to be in good physical condition the night he received the vaccine. The patient experienced malaise in the body and strange feeling. The patient was found seated on the toilet in a state of cardio-respiratory arrest. Pupillary reflex disappeared, no heart sounds or breathing sounds were heard, and no pulse was felt in the carotid artery. Cause of death was reported as painless acute myocardial infarction. Advanced age and patient´s medical history remains as confounders. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes:	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							On 22-Feb-2022: Follow up document received and contains Patient demographic information added, laboratory data added, concomitant product added and event added.	
[redacted]	ITALY	Cardio-respiratory arrest, Haemorrhage, Loss of consciousness	72.00	Male	Myocardial infarction(H)	ZOLOFT; CARDIOASPIRIN; ACESISTEM	This case was initially received via European Medicines Agency (Reference number: [redacted] on 07-Feb-2022. The most recent information was received on 16-Feb-2022 and was forwarded to Moderna on an unknown date. This regulatory authority case was reported by a physician and describes the occurrence of LOSS OF CONSCIOUSNESS (After 15 minutes after the Spikevax booster dose, the subject fell to the ground losing consciousness and beating his head, on my arrival he would emit rales, lost blood from the oral cavity and had no pulse.), CARDIO-RESPIRATORY ARREST (After 15 minutes after the Spikevax booster dose, the subject fell to the ground losing consciousness and beating his head, on my arrival he would emit rales, lost blood from the oral cavity and had no pulse.) and HAEMORRHAGE (After 15 minutes after the Spikevax booster dose, the subject fell to the ground losing consciousness and beating his head, on my arrival he would emit rales, lost blood from the oral cavity and had no pulse.) in a 72-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000033A) for COVID-19 vaccination. The patient's past medical history included Myocardial infarction old. Concomitant products included SERTRALINE HYDROCHLORIDE (ZOLOFT) for Depression, ENALAPRIL MALEATE, HYDROCHLOROTHIAZIDE (ACESISTEM) for Hypertension, ACETYLSALICYLIC ACID (CARDIOASPIRIN) for an unknown indication. On 15-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milligram. On 15-Jan-2022, the patient experienced LOSS OF CONSCIOUSNESS (After 15 minutes after the Spikevax booster dose, the subject fell to the ground losing consciousness and beating his head, on my arrival he would emit rales, lost blood from the oral cavity and had no pulse.) (seriousness criterion death), CARDIO-RESPIRATORY ARREST (After 15 minutes after the Spikevax booster dose, the subject fell to the ground losing consciousness and beating his head, on my arrival he would emit rales, lost blood from the oral cavity and had no pulse.) (seriousness criterion death) and HAEMORRHAGE (After 15 minutes after the Spikevax booster dose, the subject fell to the ground losing consciousness and beating his head, on my arrival he would emit rales, lost blood from the oral cavity and had no pulse.) (seriousness criterion death). The patient died on 28-Jan-2022. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Treatment information was not provided.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							Post vaccination , patient fell down , lost consciousness and hit his head. And patient was unconscious, unresponsive to stimuli emitted rales and had oral cavity bleeding upon arrival. Wrist art was not perceptible. Company comment: This regulatory case concerns a 72 year old male patient with relevant medical history of myocardial infarction, hypertension and concurrent use of acetylsalicylic acid and sertraline, who experienced the fatal unexpected serious events of Cardio-respiratory arrest, Haemorrhage and Loss of consciousness after receiving the unknown dose of mRNA-1273 vaccine. Medical history of myocardial infarction and concurrent hypertension could be confounding for the events. Concomitant acetylsalicylic acid and sertraline could be confounding for the event of haemorrhage. At the time of this report, the events had resolved with sequelae. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 16-Feb-2022: Upon query received from business partner, significant correction was performed on 28-FEB-2022. Events seriousness criteria was updated from Life Threatening to Fatal in the company comment. On 28-Feb-2022: Follow up received on 28-Feb-2022 contains no new information.	
[redacted]	TAIWAN, PROVINCE OF CHINA	Abdominal pain, Abdominal pain upper, Chest pain, Syncope	73.00	Female	Diabetes mellitus(C); Hypertension(C); Cardiac failure(H)	0	This regulatory authority case was reported by an other health care professional and describes the occurrence of ABDOMINAL PAIN (Abdominal Pain), SYNCOPE (Faint), ABDOMINAL PAIN UPPER (Epigastric pain , then chest pain and sudden collapse) and CHEST PAIN (Epigastric pain , then chest pain and sudden collapse) in a 73-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. The patient's past medical history included Heart failure. Concurrent medical conditions included Diabetes mellitus and Hypertension. On 14-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 16-Jan-2022, the patient experienced ABDOMINAL PAIN (Abdominal Pain) (seriousness criterion death), SYNCOPE (Faint) (seriousness criterion death), ABDOMINAL PAIN UPPER (Epigastric pain , then chest pain and sudden collapse) (seriousness criterion death) and CHEST PAIN (Epigastric pain , then chest pain and sudden collapse) (seriousness criterion death). The cause of death was not reported. It is unknown if an autopsy was performed.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. On 03-Jul-2021, the patient received the first dose of Moderna vaccine. On 05-Oct-2021, she received the second dose of Moderna vaccine. On 14-Jan-2022, she received the third dose of Moderna vaccine (booster). On 16-Jan-2022 at 15:00-16:00, she complained of epigastric pain, nausea, stomach discomfort, leg cramps, and general discomfort, followed by chest pain and sudden collapse. On the same day at 16:38, cardiac arrest occurred before arriving at the hospital. CPR was carried out for 10 minutes, but the cardiopulmonary resuscitation was ineffective, and the patient died. On 22-Jan-2022, the hospital reported the adverse event of vaccine, and the dead diagnosis would be uploaded. The Worldwide UID was reported as [redacted] CC: This regulatory authority case concerns a 73 year old female with relevant medical history of Diabetes Mellitus, hypertension and cardiac failure, received two doses of mRNA-1273 as primary series vaccine, who experienced Serious (fatal), unexpected events of abdominal pain, syncope, abdominal pain, upper and chest pain which occurred 3 days post vaccination with the 3rd dose of mRNA-1273 vaccine. On the afternoon of January 16, the patient developed right upper abdominal pain, nausea, stomach discomfort, leg cramps, chest pain, and general discomfort. This patient was brought to the hospital but the patient was already dead upon arrival at the hospital, resuscitation was done for 10 mins but the patient was not revived and declared dead. There was no reported clear statement re the cause of the death but it was mentioned that this event would be reported as an adverse event from the vaccine. It is unknown if an autopsy was done. The age of this patient and the above medical conditions are considered as confounders for this case (risk factors that can lead to a cardiovascular event). The benefit -risk relationship of mRNA -1273 (Moderna Covid 19 Vaccine) is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow-up received contains non-significant information.	
[redacted]	TAIWAN, PROVINCE OF CHINA	Headache, Syncope, Vomiting	72.00	Female	Diabetes mellitus(C); Dialysis; ASTRAZENECA COVID-19 VACCINE; ASTRAZENECA COVID-19 VACCINE	0	This regulatory authority case was reported by an other health care professional and describes the occurrence of HEADACHE (Headache), VOMITING (Vomiting) and SYNCOPE (Faint) in a 72-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Renal dialysis (Had been receiving renal dialysis in Clinic for 9 years). Previously administered products included for Product used for unknown indication: Astrazeneca and Astrazeneca.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							Past adverse reactions to the above products included Fever with Astrazeneca and Astrazeneca. Concurrent medical conditions included Diabetes mellitus (DM). On 19-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 28-Jan-2022, the patient experienced HEADACHE (Headache) (seriousness criterion death), VOMITING (Vomiting) (seriousness criterion death) and SYNCOPE (Faint) (seriousness criterion death). The reported cause of death was Headache, Vomiting and Faint. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. The patient with OHCA was admitted to the emergency department. Company Comment: This regulatory authority case concerns a 72-year-old female patient, with relevant medical history of Diabetes Mellitus and has been receiving hemodialysis procedure for nine years, who experienced the unexpected serious fatal events of Headache, Vomiting and Syncope, which occurred 9 days after receiving a dose mRNA-1273 vaccine taken as third dose of COVID-19 immunization. Interchange of vaccine products is noted in this case as patient received 2 doses of AstraZeneca COVID-19 vaccine on unspecified dates prior to mRNA-1273 administration. The events were accompanied by loss of consciousness which prompted the pre-hospital emergency response. She was noted to have no vital signs prior admission in the emergency room. Death occurred approximately 9 days after receiving the third dose of mRNA-1273 vaccine. The cause of death was reported as Headache, Vomiting and Syncope. It is unknown if an autopsy was performed. Advanced age and medical history remain as confounders for the events and for the fatal outcome. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per regulatory authority's report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow-up document received: Medical history was updated, LLT of event syncope was changed to faint and cause of death was added.	
[redacted]	TAIWAN, PROVINCE OF CHINA	Death	61.00	Male	Chronic kidney disease(C); Type 2 diabetes mellitus(C); Hypertensive heart disease(C); Hyperlipidaemia(C); Rhinitis allergic	0	This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (Death) in a 61-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Chronic kidney disease stage 3 (Chronic kidney disease, stage 3 (moderate)), Type 2 diabetes mellitus (Type 2 diabetes mellitus with other specified complication), Hypertensive heart disease (Hypertensive heart disease without	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							heart failure), Hyperlipidemia (Hyperlipidemia, unspecified) and Allergic rhinitis (Other allergic rhinitis). On 21-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. Death occurred on 25-Jan-2022 It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter considered DEATH (Death) to be related. No concomitant and treatment medications were reported. It was reported as, the patient received AZ COVID-19 vaccines on 30-Jun-2021 and 21-Sep-2021, respectively. On morning of 25-Jan-2022, the patient's family called an ambulance and sent the patient to the emergency room of the hospital as the patient was unconscious and could not be woken up. The patient stopped breathing and heartbeat before arriving at the hospital. The ambulance sent the patient to the emergency room of the hospital. The emergency room personnel performed cardiopulmonary resuscitation on the patient. The patient's family gave up on emergency treatment and the physician pronounced the patient dead. On 26-Jan-2022, administrative postmortem was carried out, cause of death was suspected acute myocardial infarction, ischemic heart disease, diabetes and hyperlipidemia. No autopsy was performed Company Comment: This is a regulatory case concerning a 61-year-old, male patient with past medical history of Chronic kidney disease stage 3, Type 2 diabetes mellitus, Hypertensive heart disease and Hyperlipidemia, who experienced the fatal event of Death, which occurred 4 days after the third dose of mRNA-1273 vaccine. On 01/26/2022, administrative postmortem was carried out. Cause of death reported as suspected acute myocardial infarction, ischemic heart disease, diabetes and hyperlipidemia. Patients past medical history of Chronic kidney disease stage 3, Type 2 diabetes mellitus, Hypertensive heart disease and Hyperlipidemia remains as a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The event was assessed as serious as per Regulatory Authority's report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow up document received contains non significant information (I narrative updated)	
[redacted]	TAIWAN, PROVINCE OF CHINA	Altered state of consciousness	87.00	Male	Diabetes mellitus(C); End stage renal disease(C); Dialysis; Coronary	0	This regulatory authority case was reported by an other health care professional and describes the occurrence of ALTERED STATE OF CONSCIOUSNESS (Changes in consciousness) in an 87-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
					artery disease(C); Stent placement		The patient's past medical history included Dialysis and Stent placement. Concurrent medical conditions included Diabetes, End stage renal failure and Coronary artery disease. On 15-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 27-Jan-2022, the patient experienced ALTERED STATE OF CONSCIOUSNESS (Changes in consciousness) (seriousness criterion death). It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Authority number-[redacted] On 15 Jan, the reporter stated patient received the Moderna booster, and then he was continually weak. Two days later, patient had abnormal liver function, increased white blood cells, and improved inflammation index after blood drawing. However, the fatigue continued. On 27 Jan, the patient received dialysis treatment in the morning. Blood pressure was normal at 8:05. At 8:15, they suddenly opened their arms and lost consciousness. After losing consciousness, their blood pressure dropped and their heart stopped. First aid was started immediately. The patient was sent to the emergency department of Hospital to continue the first aid, but the patient was declared dead. No concomitant medication was reported. No treatment information was provided. Company Comment: This regulatory authority case concerns a 87 year old male with relevant medical history of Diabetes mellitus , End stage renal disease on maintenance hemodialysis, known to have Coronary Artery disease S /P stet placement , who experienced Serious (fatal) , unexpected event of altered state of consciousness which occurred 13 days post vaccination with the 3rd dose of mRNA-1273 vaccine . This patient was reported to be continually weak after receiving the vaccine , noted abnormal liver function , increased WBC . 13 days post vaccination with the mRNA=1273 , this patient underwent hemodialysis initially had stable vital signs and after 10 mins of treatment he had loss of consciousness , the BP dropped and the heart beat stopped , Resuscitation was given . Further details regarding this event was not given . This RA case report gave two conflicting possible outcome , the seriousness criteria was captured as Fatal while th outcome was recovering , There were no other details found in the SD that can draw the conclusion because the narrative was not complete. The medical history stated above and the age of this patient are confounders for this case (all are risk factor for possible acute events that can lead to death) . The benefit -risk relationship of mRNA -1273 is not aff Most recent FOLLOW-UP information incorporated above includes:	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							On 25-Apr-2022: Follow-Up included non-significant information was added. I-narrative added.	
[redacted]	TAIWAN, PROVINCE OF CHINA	Asthma, Chest discomfort	72.00	Male	Transplant failure(H); Coronary artery disease(C); Mitral valve incompetence(C); Coronary artery bypass; Coronary arterial stent insertion; End stage renal disease(C); Stent placement; ASTRAZENECA COVID-19 VACCINE; Dialysis; Stent placement(H)	0	This case was initially received via an unknown source (no reference has been entered for a health authority or license partner) on 07-Feb-2022. The most recent information was received on 25-Apr-2022 and was forwarded to Moderna on 25-Apr-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of ASTHMA (Respiratory asthma) and CHEST DISCOMFORT (chest tightness) in a 72-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Graft failure (SVG failure), Stent placement (cardiac catheter stent was implanted), CABG (s/p CABG with SVG failure), Bare metal coronary stent placement (s/p DES to proximal and mid LAD and BMS to distal LAD, with ISR in DES in p- and m-LADs/p DEB and BMS, s/p BMS to distal LAD.), Drug-eluting stent placement (s/p DES to proximal) and Dialysis since an unknown date. Previously administered products included for Product used for unknown indication: Aztrazenica. Past adverse reactions to the above products included Chest tightness with Aztrazenica. Concurrent medical conditions included Coronary artery disease (CAD, 3VD) since January 2020, Mitral regurgitation (Moderate) and End stage renal disease (ESRD) (on HD135). On 10-Jan-2022, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 11-Jan-2022, the patient experienced ASTHMA (Respiratory asthma) (seriousness criterion death) and CHEST DISCOMFORT (chest tightness) (seriousness criterion death). The patient was treated with NITROGLYCERIN at an unspecified dose and frequency. The reported cause of death was respiratory asthma, Chest tightness, Heart failure and Kidney failure. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 11-Jan-2022, Blood pressure measurement: 91/60 (Low) 91/60 mmHg and 119/76 119/76 mmHg. On 11-Jan-2022, Body temperature: 36.2 36.2°C;. On 11-Jan-2022, Coma scale: e2v1m3 E2V1M3. On 11-Jan-2022, Electrocardiogram: standstill standstill. On 11-Jan-2022, Heart rate: 86 86 BPM. On 11-Jan-2022, Oxygen saturation: 82 82%, and after O2 mask was used, 88 88%, 92 92% and 82 82%. On 11-Jan-2022, Respiratory rate: 36-38 36-38 times/min and 32 32 times/min. On 11-Jan-2022, Vital signs measurement: had no vital signs had no vital signs.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. Company comment: This fatal regulatory authority case concerns a 72-year-old male patient, with medical history of graft failure (reported as SVG failure), coronary artery bypass, bare metal coronary stent placement, coronary artery disease, mitral regurgitation and drug-eluting stent placement, who experienced the serious (due to death) unexpected events of ASTHMA and CHEST DISCOMFORT, on the following day he received a dose of mRNA-1273 vaccine, considered as the second dose of the vaccination schedule, and died on the same day that the events occurred. he previously received, on an unknown date, a dose of AstraZeneca'S COVID-19 vaccine. According to the narrative of the source document, on the following day of the vaccination with mRNA-1273, his USUAL? renal dialysis, due to his end stage renal disease, HAD TO be suspended because of chest discomfort, dyspnea, desaturation and heart rate increased, for what he was sent to the emergency room, where a severe lung edema was found. his electrocardiogram showed standstill and the patient lost his vital signs. The reported cause of death was a natural death due to his heart and kidney failure and the doctor stated that it did not seem to be an acute heart discomfort caused by the vaccination. It is unknown if an autopsy was performed. The history of graft failure, coronary artery bypass, bare metal coronary stent placement, coronary artery disease, mitral regurgitation and drug-eluting stent placement remain as confounders for chest discomfort. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow-up document contains added cause of death, medical history, lab data, treatment medication, deleted an event (shortness of breath), added new event (respiratory asthma) and updated I-narrative.	
[redacted]	TAIWAN, PROVINCE OF CHINA	Abdominal pain, Altered state of consciousness	75.00	Male	Myocardial ischaemia(H); Essential hypertension(H); End stage renal disease(H); Colon cancer stage II(H); Haemodialysis	0	This regulatory authority case was reported by an other health care professional and describes the occurrence of ABDOMINAL PAIN (Abdominal pain) and ALTERED STATE OF CONSCIOUSNESS (Changes in consciousness) in a 75-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 050F21A_1110124-CDC) for COVID-19 vaccination. The patient's past medical history included Chronic ischemic heart disease, unspecified, Essential hypertension (Primary), End stage renal disease (ESRD) (ESRD under Hemodialysis), Colon cancer stage II (S-D junction colon cancer (pT3N0M0,stage IIA)) and Hemodialysis (ESRD under Hemodialysis). On 11-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) .5 milliliter. On 17-Jan-2022, the patient experienced ABDOMINAL PAIN	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							(Abdominal pain) (seriousness criterion death) and ALTERED STATE OF CONSCIOUSNESS (Changes in consciousness) (seriousness criterion death). It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications were not provided. The patient received the first dose of Astrazeneca vaccine on 17-Jun-2021. The patient received the second dose of Astrazeneca vaccine on 28-Sep-2021, and received the third dose of Moderna vaccine on 01-Jan-2022. On 11-Jan-2022, at 09:34 A.M, the patient received booster dose of Moderna vaccine. The patient had sought medical treatment at the Emergency room of the hospital due to abdominal pain for five days. The patient had undergone some blood tests and results were as follows : Creatinine (B): 7.24(mg/dL), eGFR (Glomerular filtration rate): 7.4 (ml/min/1.73 m^2), Na (sodium): 134 (meq/L), CRP (C-reactive protein): 21.43 (mg/dL), WBC: (white blood cells): 15.6 (10 ^3/uL), Hb (hemoglobin): 9.5 (g/dL). The patient had undergone CT scan of abdomen (display) and result found was right pleural effusion, left lower lobe pneumonia, bilateral renal calculi and ruled out the possibility of spleen inflammation. Patient was treated with 0.9 percent saline (500ml/bag) 500ml IVD STAT, 0.9 percent saline (500mL/bag) 100mL+Flomoxef (1g/vial) 1000mg STAT IVD, Ketorolac (30mg/amp) 30mg STAT IVP . The patient was suggested to receive a treatment at hospital after consultation with the emergency physician. On 17-Jan-2022, the patient sought medical treatment at the Emergency Room due to abdominal pain for five days. On 17-Jan-2022, the COVID-19 PCR test came back as negative, with abnormal CK-MB and Troponin I values, right pleural effusion, left lower lobe pneumonia, bilateral renal calculi and ruled out possibility of spleen inflammation. The patient was admitted to the hospital for treatment. Company comment-This regulatory authority case concerns a 75 year old male , with relevant medical history of hypertension, chronic ischemic heat disease (unspecified) , End stage renal dsease on maintenance hemodialysis , Colon CA stage 2 , initially vaccinated with 2 doses of Covid 19 vaccine Astra Zeneca, who experienced Serious (fatal) , unexpected events of abdominal pain and altered state of consciousness which occurred 10 days post vaccination with the 3rd dose of mRNA-1273 vaccine . This patient was seen at the General hospital ER because of abdominal pain occurring for the past 5 days. Laboratories were	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							done noted to have increased Serum creatinine , decreased hemoglobin , increased WBC and CRP . Treatment given was I V saline with Flomoxef and I V ketorolac. Ct scan of the abdomen was done which revealed : Right pleural effusion, left lower lobe pneumonia, bilateral renal calculi and r/o spleen inflammation. The patient was advised admission at the hospital . RT PCR test done which revealed negative results. One day after there was increased chest and abdominal pain and shortness of breath. The physician did 12L ECG, X-ray, and blood tests K: 4.3 (meq/L), CK: 104 (U/L), CK-MB (mass): 22.5 (ng/mL), Troponin I: 4404.5 (pg/mL), D-dimer: 6.680 (mg/L, with an impression of Myocardial infarction, nitroglycerin (NTG)0.6mg 1# ST PO was given. The assessment of Chest x-ray showed suspected aortic dissection so a CT scan of the abdomen was done which revealed negative for dissection however this patient's sensorium deteriorated transferred to ICU , brain CT scan revealed Subarrachnoid hemorrhage , referred to neurosurgery service and surgery was done , post operation patient still had elevations in trop I and CPKMB, this patient went to Cardiac arrest , CPR done however it was not successful and this patient died after three days of hospitalization. The age of this patient , history of vaccinatiojn for 2 doses with Covid 19 Vaccine Astra Zeneca and the above medical conditions are considered as confounders for this case. The benefit -risk relationship of mRNA -1273 (Moderna Covid 19 Vaccine) is not affected by this report. Also dosage for this booster dose was reported as 0.5mL not the recommended 0.25mL booster dose, hence Accidental overdose occurred. The Worldwide UID was reported as [redacted] Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow Up received is non significant.	
[redacted]	GERMANY	Death, Influenza like illness	78.00	Female	Atrial fibrillation(H); Quadriplegia(H); Pulmonary fibrosis(H); COVID-19(H); Venous thrombosis limb(H); Myopathy(H); COMIRNATY	0	This case was received via European Medicines Agency (Reference number: [redacted] on 09-Feb-2022 and was forwarded to Moderna on 09-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of DEATH (found dead by the husband in the morning (23.01.22).) in a 78-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 216045) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Tachyarrhythmia absoluta, Tetraplegia, Lung fibrosis, COVID-19 in February 2021, Leg venous thrombosis in 2017 and Myopathy. Previously administered products included for Prophylactic vaccination: Comirnaty BNT162b2 on 30-Jul-2021. Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							On 22-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 3 dosage form. On 22-Jan-2022, the patient experienced INFLUENZA LIKE ILLNESS (Strong freezing, nausea and vomiting, after a few hours of improvement, went to bed). The patient died on an unknown date. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, INFLUENZA LIKE ILLNESS (Strong freezing, nausea and vomiting, after a few hours of improvement, went to bed) had not resolved. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant medications details were not reported by the reporter. Treatment details was not reported by the reporter. Company comment: This case concerns a 78-year-old female patient with medical history of Tachyarrhythmia absoluta, Tetraplegia, Lung fibrosis, COVID-19 in February 2021, Leg venous thrombosis in 2017 and Myopathy, who died on unknown date after administration of mRNA-1273. The cause of death was not reported. It is unknown if an autopsy was performed. It was also reported that the patient experienced non-serious INFLUENZA LIKE ILLNESS on the same day after vaccine administration. The patient's medical history of Tachyarrhythmia absoluta, Tetraplegia, Lung fibrosis and Leg venous thrombosis remain strongly confounding. The reporter did not provide causality assessment. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Having in mind that this patient received the COVID-19 VACCINE PFIZER prior to vaccination with the company product, Interchange of vaccine products should have been considered in this specific case.	
[redacted]	SPAIN	Hyperthermia malignant	75.00	Female	Obesity(C); Depression(C); Atrial fibrillation(C); Hypoacusis(C); Chronic obstructive pulmonary disease(C); Arteriosclerosis(C); Dyslipidaemia(C); Diabetes mellitus(C)	TRANGOREX; DOBUPAL; BISOPROLOL EG; SPIOLTO; SPIRONOLACTONE; TRUSOPT; DEPRAX [FLUOXETINE HYDROCHLORIDE]; ATORVASTATINA MK; VESICARE; AMLODIPINO RAAM	This case was received via European Medicines Agency (Reference number: [redacted] on 09-Feb-2022 and was forwarded to Moderna on 09-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of HYPERTHERMIA MALIGNANT (Malignant hyperthermia) in a 75-year-old female patient who received mRNA-1273 (Spikevax) (batch no. W0539-1) for COVID-19 vaccination. Concurrent medical conditions included Morbid obesity, Depression, Fibrillation paroxysmal atrial, Hypoacusis, COPD, Atheromatosis (severe aortic artery with ulcerated plaque and hematoma at the level of the abdominal aorta), Dyslipidaemia and Diabetes. Concomitant products included VENLAFAXINE HYDROCHLORIDE (DOBUPAL) from 09-May-2018 to an unknown date and FLUOXETINE HYDROCHLORIDE (DEPRAX [FLUOXETINE HYDROCHLORIDE]) from 28-Jan-2016 to an unknown date for Adjustment reaction with prolonged depressive reaction, ATORVASTATIN CALCIUM (ATORVASTATINA MK) from 31-May-2019 to an unknown	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							date for Aortic valve disease, AMIODARONE HYDROCHLORIDE (TRANGOREX) from 02-Apr-2014 to an unknown date and BISOPROLOL FUMARATE (BISOPROLOL EG) from 01-Apr-2014 to an unknown date for Atrial fibrillation, OLODATEROL HYDROCHLORIDE, TIOTROPIUM BROMIDE MONOHYDRATE (SPIOLTO) from 24-Aug-2017 to an unknown date for Chronic bronchitis, AMLODIPINE MALEATE (AMLODIPINO RAAM) from 23-Aug-2017 to an unknown date for Essential hypertension, SPIRONOLACTONE from 02-Apr-2014 to an unknown date for Heart failure, DORZOLAMIDE HYDROCHLORIDE (TRUSOPT) from 16-May-2017 to an unknown date for Ocular hypertension, SOLIFENACIN SUCCINATE (VESICARE) from 26-Oct-2017 to an unknown date for Urine incontinence. On 18-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Subcutaneous) 1 dosage form. On an unknown date, after starting mRNA-1273 (Spikevax), the patient experienced HYPERTHERMIA MALIGNANT (Malignant hyperthermia) (seriousness criterion death). The reported cause of death was Hyperpyrexia malignant. It is unknown if an autopsy was performed. mRNA-1273 (Spikevax) (Subcutaneous) dosing remained unchanged. For mRNA-1273 (Spikevax) (Subcutaneous), the reporter did not provide any causality assessments. Treatment information was not provided. Time Interval between Beginning of Drug Administration and Start of Reaction / Event was 2 days. Company comment: This case concerns a 75-year-old female patient with medical history of Morbid obesity, Depression, Fibrillation paroxysmal atrial, Hypoacusis, COPD, Atheromatosis, Dyslipidaemia, Diabetes, Essential hypertension and Heart failure who experienced serious unexpected event of malignant hyperthermia and subsequently died. Very limited information provided precluding comprehensive assessment. The event occurred two days after the dose of mRNA-1273. The reported cause of death was Hyperpyrexia malignant. It is unknown if an autopsy was performed. Causality is confounded with concomitant use of Atorvastatin. Furthermore, patient's advanced age and significant medical history could have contributed to the fatal outcome. The benefit-risk relationship of mRNA-1273 is not affected by this report. Incorrect route of product administration should have been considered in this particular case as the vaccine was administered by subcutaneous route.	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							Most recent FOLLOW-UP information incorporated above includes: On 09-Feb-2022: Translation received on 15-Feb-2022 includes Event description, concomitant medication reported by the Primary Source Translated and narrative was updated accordingly.	
[redacted]	UNITED STATES	Anaphylactic reaction	68.00	Female	Hypertension(C); Hypersensitivity; Bronchial hyperreactivity(C) ; Anaphylactic reaction(H); ALBUTEROL HFA(H); ALBUTEROL HFA(H)	0	This spontaneous case was reported by a consumer and describes the occurrence of ANAPHYLACTIC REACTION (anaphylaxis due to COVID-19 vaccination) in a 68-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Anaphylactic reaction to drug (Albuterol). Previously administered products included for Wheezing: Albuterol; for Shortness of breath: Albuterol. Past adverse reactions to the above products included Allergic reaction with Albuterol and Albuterol. Concurrent medical conditions included Hypertension, Environmental allergy and Reactive airways disease. On 23-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 23-Mar-2021, the patient experienced ANAPHYLACTIC REACTION (anaphylaxis due to COVID-19 vaccination) (seriousness criteria death, hospitalization and medically significant). The patient was hospitalized from 23-Mar-2021 to 24-Mar-2021 due to ANAPHYLACTIC REACTION. The patient died on 24-Mar-2021. The reported cause of death was anaphylaxis due to covid-19 vaccination. An autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 23-Mar-2021, Heart rate: lost pulses (abnormal) lost pulses. No concomitant medications were reported. No treatment medications were reported. It was reported that the patient struggled to breathe after receiving her first Moderna vaccine. She was taken to the hospital and died the next day. The autopsy says she had a medical history of hypertension, environmental allergies and reactive airway disease (not asthma), with previous anaphylactic reaction to Albuterol. The patient started to have reaction 15 to 20 minutes after receiving the vaccine. She began to complain of feeling as though her airway was becoming blocked. She had severe respiratory distress with labored breathing and stridor and poor oxygen saturation. She was intubated and taken to the emergency room. Upon arrival to the hospital, she was reintubated for airway tube	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							positioning and lost pulses. CPR was initiated and return of spontaneous circulation was achieved but her condition continued to decline. The family elected not to have her resuscitated at 11:40 a.m. on March 24, 2021. She dies at 11:55 a.m. The patients autopsy revealed she had a history of allergic reactions which caused her throat to close. Company comment: This spontaneous case concerns a 68-year-old female patient with relevant medical history of environmental allergy, anaphylactic reaction to albuterol and reactive airway disease, who experienced serious, unexpected event of Anaphylactic reaction. The event is assessed as unexpected due to fatal outcome. The first symptoms of the event occurred 15-20 minutes after the 1st dose of mRNA-1273. It was reported that 15-20 min after the vaccination, the patient complained of airway obstruction as she struggled to breathe followed by the occurrence of stridor and poor oxygen saturation. She also had throat closing sensation. The patient was intubated and taken to the emergency room. for respiratory distress. Upon arrival, the patient was reintubated for airway tube positioning and lost pulses. The CPR was performed and return of spontaneous circulation was achieved, but her condition continued to decline. The family decided on not to be resuscitated. The reported cause of death was "anaphylaxis due to COVID-19 vaccination" as per the autopsy report. The medical history of reactive airway disease, environmental allergy and anaphylactic reaction to medication are possible confounders. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 10-Feb-2022: Live follow-up received Past medical historical information was updated. On 14-Feb-2022: Follow-up received contains additional significant information that include newevent (throat to close) and new reporter. Hypertension and reactive airway disease had been updated to current conditions. Event anaphylaxis is updated to anaphylactic reaction to vaccine. Events respiratory distress, dyspnoea, stridor, oxygen saturation decreased and condition aggravated were subsumed under event anaphylactic reaction to vaccine.	
[redacted]	SWITZERLAND	Cardiac arrest, Sudden cardiac death	80.00	Female	Dementia Alzheimer's type(C)	EXELON [RIVASTIGMINE]; ESCITALOPRAM	This regulatory authority case was reported by a consumer and describes the occurrence of CARDIAC ARREST (sudden cardiac death) and SUDDEN CARDIAC DEATH (sudden cardiac death) in an 80-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. Concurrent medical conditions included Alzheimer's disease. Concomitant products included RIVASTIGMINE (EXELON [RIVASTIGMINE]) and ESCITALOPRAM for an unknown indication. On 01-Dec-2021, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							once a day. On 08-Dec-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced CARDIAC ARREST (sudden cardiac death) (seriousness criteria death and medically significant) and SUDDEN CARDIAC DEATH (sudden cardiac death) (seriousness criteria death and medically significant). The patient died on 08-Dec-2021. The reported cause of death was Cardiac arrest. An autopsy was not performed. No allergy reported, no alcohol consumption reported, non-smoker. No cardiovascular disease reported. There were no recent acute events reported. Chronically taken Exelon and Escitalopram (unspecified dosages). The patient received the booster dose with Spikevax vaccine on 01 Dec 2021. No information on previous doses known. Lot not known. The patient tolerated vaccination well (no acute adverse reactions were reported). However, on 08 Dec 2021, or one week after the booster vaccination, the sudden death of the patient was reported, probably in the context of cardiac arrest (relatively unexpected sudden death, most likely sudden cardiac death. The attending physician wrote as the cause of death- sudden heart failure). No autopsy was performed. No treatment medications were reported. Company comment: This is a regulatory case concerning an 80 year-old, female patient with a history of Dementia Alzheimer's type and concomitant use of Escitalopram, who experienced the serious Fatal unexpected, AESI of sudden cardiac death and the event cardiac arrest, approximately 7 days after the booster dose of mRNA-1273 vaccine. The patient died 7 days after vaccination, on the onset date of the events, no autopsy was performed and the cause of death was reported as cardiac arrest. The event was considered unrelated to the vaccine per the reporter's assessment. The mentioned medical history, concomitant medication and patient's advanced age remain as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. sudden heart death/sudden heart failure	
[redacted]	SWITZERLAND	Death	77.00	Male	Tobacco user(C); Lung neoplasm malignant(C); Colon cancer(C); Hypercholesterolaemia(C); Diabetes mellitus(H)	PREDNISONE TEVA; ACIDUM FOLICUM; SIMCORA; DUODART; EFFORTIL; SOLARAZE; DAFALGAN	This regulatory authority case was reported by a physician and describes the occurrence of DEATH (Cause of death unknown, suspected cardiac arrest) in a 77-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. The patient's past medical history included Diabetes (Type II diabetes resolved as a result of weight loss in oncological context). Concurrent medical conditions included Smoker (Tobacco: yes), Lung cancer, Colon cancer (Recently diagnosed colonic cancer.) and Hypercholesteraemia.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							Concomitant products included PREDNISONE (PREDNISONE TEVA) from 26-Feb-2021 to an unknown date, FOLIC ACID (ACIDUM FOLICUM), SIMVASTATIN (SIMCORA), DUTASTERIDE, TAMSULOSIN HYDROCHLORIDE (DUODART), ETILEFRINE HYDROCHLORIDE (EFFORTIL), DICLOFENAC SODIUM (SOLARAZE) and PARACETAMOL (DAFALGAN) for an unknown indication. On 03-Dec-2021, the patient received third dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form once a day. Death occurred on 04-Dec-2021 The patient died on 04-Dec-2021. An autopsy was not performed. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered DEATH (Cause of death unknown, suspected cardiac arrest) to be unlikely related. Patient was taking medications (unknown dosage and starting date of therapy, assumed to have been taken for some time): prednisone 5 mg, folic acid 5 mg, Simcora 5 mg, Duodart 0.5/0.4 mg, Effortil 10 drops as required, Solaraze gel 3%, Dafalgan 1 g as required. The first dose of Spikevax was performed on 27 Jan 2021 (lot 300042460 indicated), the second dose on 26 Feb 2021 (lot 300042723 indicated) and the third booster dose on 03 Dec 2021 (lot unknown). The day after the third dose (04 Dec) the patient died, cause unknown, probably from heart disease. There is no death / autopsy letter available. Despite the suggestive temporal correlation, considering the numerous risk factors presented by the patient, his age, in the absence of further information, the causal link is judged as unlikely. No treatment medications were provided. Company comment: This is a regulatory case concerning a 77 year-old, male patient with a history of Lung neoplasm malignant, Colon cancer, Tobacco user, Hypercholesterolaemia, Diabetes mellitus and polypharmacy, who experienced the serious Fatal unexpected, event of death (reported as cause of death unknown, suspected cardiac arrest), approximately 1 day after the booster dose of mRNA-1273 vaccine. Cause of death was reported as probably from heart disease, an autopsy was not performed. The event was considered unrelated to the vaccine per the reporter's assessment. The mentioned medical history and patient´s advanced age remain as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 09-Feb-2022: Translation received on 15-Feb-2022 included event verbatim and dosage text was updated.	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
[redacted]	FRANCE	Death	73.00	Male	Arterial stent insertion; Cardiac failure(H); Hypertensive heart disease(H); Pulmonary oedema(H)	0	This case was received via European Medicines Agency (Reference number [redacted] on 10-Feb-2022 and was forwarded to Moderna on 10-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (Death NOS) in a 73-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 057G21A) for COVID-19 vaccination. The patient's past medical history included Insufficiency cardiac, Hypertensive heart disease NOS, Pulmonary oedema and Arterial stent insertion. On 14-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form once per month. Death occurred on 19-Dec-2021 The patient died on 19-Dec-2021. The reported cause of death was death related to cardiovascular pathology. An autopsy was not performed. No concomitant medications were reported. No treatment medications were reported. Company comment: This is a regulatory authority case concerning a 73-year-old, male patient with relevant medical history of arterial stent insertion, cardiac insufficiency, hypertensive heart disease NOS and pulmonary edema, who experienced the unexpected serious event of death NOS. The event death NOS occurred approximately 5 days after the unknown dose number of mRNA-1273 vaccine administration. The reported cause of death was death related to cardiovascular pathology. It was unknown if autopsy was done. The medical history of arterial stent insertion, cardiac insufficiency, hypertensive heart disease NOS and pulmonary edema remain confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	[redacted]
[redacted]	SWITZERLAND	Asthenia, Death, Head injury	85.00	Male	Renal impairment(C); Metastatic malignant melanoma(C); Hypochromic anaemia(C); Urinary tract infection(H); Ischaemic cardiomyopathy(H); Cardiac pacemaker insertion; Gout(H); Drug hypersensitivity;	0	This regulatory authority case was reported by a physician and describes the occurrence of HEAD INJURY (Head trauma on falling at home), ASTHENIA (Severe asthenia) and DEATH (Death) in an 85-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. The patient's past medical history included Urinary infection (Infection treated) from 31-Oct-2021 to 07-Nov-2021, Ischemic cardiomyopathy (Chronic ischemic heart disease on monovasal, arrhythmic coronary heart disease on atria fibrillation), Gout, Peripheral obliterative arteriopathy (Leriche-Fontaine Stage II Peripheral Obliterating Arterial Disease) and Cardiac pacemaker insertion (Pacemaker dual-chamber pocket infection, generator change in 2009 generator change in 2017) in 2008. Concurrent medical conditions included Chronic renal impairment (Chronic Kidney Disease Stage Ga3 sec. KDIGO),	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
					Peripheral venous disease(C); Peripheral arterial occlusive disease(H)		Metastatic malignant melanoma (Melanoma in right forearm with lymph node metastases, suspected secondary disorders in liver) in 2019, Anemia hypochromic (Moderate Normocytic Hypochromic Anemia), Drug allergy (amoxicillin) and Chronic venous insufficiency. On 15-Jun-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form once a day. On 15-Jun-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form once a day. On 16-Dec-2021, received third dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form once a day. On 17-Dec-2021, the patient experienced HEAD INJURY (Head trauma on falling at home) (seriousness criteria death, hospitalization and medically significant) and ASTHENIA (Severe asthenia) (seriousness criteria death, hospitalization and medically significant). The patient died on 18-Dec-2021. An autopsy was not performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 17-Dec-2021, Blood test: normocytic normochromic anemia (abnormal) normocytic normochromic anemia and worsening of known kidney disease (abnormal) worsening of known kidney disease. On 17-Dec-2021, Chest scan: pleural effusion (abnormal) mild right-sided pleural effusion. On 17-Dec-2021, Computerised tomogram head: brain hemorrhage ruled out Brain hemorrhage ruled out. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered ASTHENIA (Severe asthenia) to be possibly related and HEAD INJURY (Head trauma on falling at home) and DEATH (Death) to be unlikely related. On Dec 17, the patient went to the emergency room for profuse asthenia and dropped at home (not clear the dynamics) with consequent head trauma (head injury following fall at home). The patient was hemodynamically stable, without fever, objective examination without particularities. It manifests occipital and ear swelling (probably after falling) and dehydration of the skin and mucous membranes. The patient had a Palliative Performance Scale of 50 percent and Palliative Prognostic Score of B, Charlson Comorbidity Index of 14 (age factored) and l'indice di Barthel for daily activities of 50. Rated as patient B stable. The patient was admitted to palliative care with symptomatic treatment of disorders. Suspended therapy with Torasemide (for dehydration) and set hydration and potassium for intravenous. The patient's condition worsens rapidly, the patient becomes more asthenic and hypothesive, with	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							hyporeacting pupils and vesicular murmure. On the day Dec 18, the patient was dead, without showing signs of suffering. The UptoDate database describes asthenia following the Comirnaty vaccine, the other Pfizer mRNA vaccine [1]. However, Spikevax's adverse reactions include fatigue that may have contributed to the development of asthenia. It should be considered that the patient, known for advanced metastatic melanoma and chronic renal failure, was already heavily weakened by his pre-existing pathological condition. Cannot ruled out that the vaccine may have contributed to increasing asthenia. The exact dynamics of the fall that caused the head injury was unknown and the cause of death has not been defined, so it was difficult to relate these events to the vaccine. It can only be speculated that death occurred due to the pathological conditions presented for a long time by the elderly patient such as metastatic melanoma, renal failure, etc. Therefore, considering the close time correlation, the data in monograph, but not being able to exclude the patient's previous condition, the causal link with asthenia is considered possible. Otherwise, in the absence of further details on the dynamics of the fall and the cause of death, considering the numerous risk factors presented by the patient and his age, despite the plausible time correlation, a relationship between vaccine and head trauma and death is unlikely. On Dec 17, the patient went to the emergency room due to severe asthenia and a fall at home with consequent head injury. The patient was hemodynamically stable, with no fever; physical examination with no specific findings. The patient had swollen occipital lymph nodes and swollen ear (likely following the fall) and dehydrated skin and mucous membranes. The patient presented with a Palliative Performance Scale of 50% and Palliative Prognostic score of B, Charlson Comorbidity Index of 14 (age factored) and Barthel Index for daily activities of 50. Assessed as stable B patient. The patient was hospitalized under palliative care with symptomatic treatment for his conditions. Most recent FOLLOW-UP information incorporated above includes: On 09-Feb-2022: Translation received on 15-Feb-2022: Event, medical history, lab, narrative updated. Company comment: This case concerns a 85-year-old male patient, with medical history of Ischemic cardiomyopathy (with arrhythmic coronary heart disease on atria fibrillation), Peripheral obliterative arteriopathy, cardiac pacemaker, Chronic renal impairment, Metastatic malignant melanoma and Chronic venous insufficiency, who experienced the unexpected events of head injury, asthenia and death, considered serious per seriousness criteria of death, hospitalization and medically significant. The events occurred approximately 1 day after the third dose of mRNA-1273, and the patient died 2 days after third dose. As reported, the patient went to the emergency room for profuse asthenia and fall at home with consequent head trauma. The patient was hemodynamically stable, without fever, objective examination without particularities and manifested occipital and	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							car swelling (probably after falling) and dehydration of the skin and mucous membranes, as reported. On computerised tomogram brain hemorrhage was ruled out. The patient was admitted for palliative care, his condition worsened rapidly, the patient became more asthenic and hypotensive and died. An autopsy was not performed. Per reporter, the likely cause of death was metastatic melanoma. Above mentioned multiple comorbidities remain as additional confounders. The benefit-risk relationship of mRNA-1273 is not affected by this report.	
[redacted]	GERMANY	Pneumonitis, Respiratory failure	61.00	Male	Chronic obstructive pulmonary disease(H)	0	This case was initially received via European Medicines Agency (Reference number: [redacted] on 14-Feb-2022. The most recent information was received on 07-Apr-2022 and was forwarded to Moderna on 07-Apr-2022. This regulatory authority case was reported by a physician and describes the occurrence of RESPIRATORY FAILURE (Pulmonary failure) and PNEUMONITIS (Pneumonitis) in a 61-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 045G21A and 3004500) for COVID-19 vaccination. The patient's past medical history included Chronic obstructive lung disease. On 01-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 22-Dec-2021, received dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 2 dosage form. On 31-Dec-2021, the patient experienced RESPIRATORY FAILURE (Pulmonary failure) (seriousness criteria death, hospitalization and life threatening) and PNEUMONITIS (Pneumonitis) (seriousness criteria death, hospitalization and life threatening). The patient died on 18-Jan-2022. The reported cause of death was Pulmonary failure. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitants were reported. No treatment information was reported. Company comment:This is a fatal case from Regulatory Authority that concerns a 61-year-old male patient, with medical history of chronic obstructive lung disease, who experienced the unexpected serious (due to death, life threatening, hospitalization) and fatal events of RESPIRATORY FAILURE and PNEUMONITIS, 9 after the second dose of mRNA-1273 vaccine. No details about previous doses were provided. He died 27 days after the vaccination, and it is unknown if an autopsy was performed. Cause of death was reported as pulmonary failure. The history of chronic obstructive lung disease remains a confounder. No further clinical information was provided for medical reviewing. The benefit-risk relationship of mRNA-1273 is not affected by this report. The seriousness was assessed as per regulatory authority report.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							Most recent FOLLOW-UP information incorporated above includes: On 07-Apr-2022: updated Medical History.	
[redacted]	GERMANY	Cough, Haemoptysis, Sudden death	65.00	Male	Hypertension(H); Chronic obstructive pulmonary disease(H)	0	This case was received via European Medicines Agency (Reference number: [redacted]) on 14-Feb-2022 and was forwarded to Moderna on 14-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of COUGH (Coughing), SUDDEN DEATH (Sudden death unexplained) and HAEMOPTYSIS (Sputum bloody) in a 65-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 092F21A) for COVID-19 vaccination. The patient's past medical history included Hypertension and COPD. On 19-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 11-Jan-2022, the patient experienced COUGH (Coughing) (seriousness criterion death) and HAEMOPTYSIS (Sputum bloody) (seriousness criterion death). The patient died on 14-Jan-2022. The cause of death was not reported. An autopsy was not performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medication was reported. No treatment information was reported. Company Comment: This regulatory authority case concerns a 65-year-old male patient, with relevant medical history of Hypertension and COPD, who experienced the unexpected serious events of Cough and Hemoptysis. The events occurred approximately 23 days after receiving a dose of mRNA-1273 Vaccine which resulted to Sudden death. The cause of death was not reported. An autopsy was not performed. The patient's medical history of Hypertension and COPD remain as confounders for the occurrence of the events. Event seriousness assessed as per Regulatory Authority report. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.	[redacted]
[redacted]	JAPAN	Cardio-respiratory arrest, Drowning, Vaccination site pain	90.00	Female	Hypertension(C); Diabetes mellitus(C); Lacunar infarction(C); Gastrooesophageal reflux disease(C); Spinal compression fracture(H)	ATELEC; MICARDIS; ALDACTONE A; TAKEPRON; PLETAAL; METGLUCO; GASMOTIN SR; RIKKUNSHITO [ATRACTYLODES LANCEA RHIZOME;CITRUS AURANTIUM	This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted]) on 14-Feb-2022. The most recent information was received on 03-Mar-2022 and was forwarded to Moderna on 08-Mar-2022. This case was reported by a physician via the Drug Information Center. On 03-Mar-2022, follow-up information was received from a physician. On an unknown date, the patient received the 1st dose of this vaccine. On an unknown date, the patient received the 2nd dose of this vaccine. On 10-Feb-2022, the patient was in drug treatment in the reporting hospital for hypertension and was in good general condition. At 09:18, the patient received the 3rd	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
						PEEL;GLYCYRRHIZA SPP. ROOT;PANAX GINSENG ROOT;PINELLIA TERNATA TUBER;PORIA COCOS SCLEROTIUM;ZINGIB ER OFFICINALE RHIZOME;ZIZIPHUS JUJUBA FRUIT]	dose of this vaccine after a medical interview. The patient's physical condition did not change after returning home. On 11-Feb-2022, around 09:00, the patient woke up. The patient had mild pain at the vaccination site but did not feel any change in physical condition and spent time as usual. Around 16:00, the patient took a bath. A family member accompanied the patient, but there was no change in the patient's complexion or movements. After 17:00, the family member went to check on the patient, who was found submerged in the bathtub. An ambulance call was made, and the patient was transported to a hospital. The patient was in cardio-respiratory arrest when the ambulance team arrived, and resuscitation was attempted, but there was no recovery. At 17:30, the patient was confirmed dead. The cause of death was drowning. No autopsy was performed. On an unknown date, an autopsy was carried out by the police, and drowning was suspected. The outcome of mild pain at the vaccination site was unknown. The outcome of cardio-respiratory arrest was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: The reporting hospital did not examine the patient for death, but the autopsy by the police suspected drowning. Follow-up received on 03-MAR-2022 Updated: Reporter Information, Patient Information, Other Relevant History, Product Information, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship. Reporter's comments: There is no temporal relationship between the occurrence of adverse events and the timing of administration of this vaccine. The occurrence of adverse events is not related to concomitant drugs. The occurrence of adverse events is not related to pathological factors of underlying disease and complications. The cause of death is not related to adverse events. The cause of death is not related to adverse events. See "narrative" section	
[redacted]	ITALY	Acute kidney injury, Aphasia, Bladder sphincter atony, Cerebrovascular accident, Coma, Pneumonia, Respiratory failure, Septic shock	87.00	Male	Chronic obstructive pulmonary disease(C); Hypertension(C); Cognitive disorder(H); Chronic kidney disease(C); COMIRNATY; COMIRNATY	NORVASC; KANRENOL; TRITTICO; QUETIAPINE; FOSTER [PIROXICAM]	This case was initially received via European Medicines Agency (Reference number: [redacted] on 14-Feb-2022. The most recent information was received on 22-Feb-2022 and was forwarded to Moderna on 22-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of RESPIRATORY FAILURE (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA), PNEUMONIA (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA), CEREBROVASCULAR ACCIDENT (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA), COMA (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA), BLADDER SPHINCTER ATONY (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA), ACUTE KIDNEY INJURY (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA), SEPTIC SHOCK (sphincter release,	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) and APHASIA (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) in an 87-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3006322) for COVID-19 vaccination. The patient's past medical history included Neurocognitive deficit (MMSE 13/30) on 01-Apr-2021. Previously administered products included for SARS-CoV-2 vaccination: COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03) on 02-Apr-2021 and COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03) on 23-Apr-2021. Past adverse reactions to the above products included No adverse event with COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03) and COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03). Concurrent medical conditions included COPD, Hypertension arterial and Renal failure chronic. Concomitant products included AMLODIPINE BESILATE (NORVASC), POTASSIUM CANRENOATE (KANRENOL), TRAZODONE HYDROCHLORIDE (TRITTICO), QUETIAPINE and PIROXICAM (FOSTER [PIROXICAM]) for an unknown indication. On 23-Nov-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On 21-Jan-2022, the patient experienced RESPIRATORY FAILURE (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death), PNEUMONIA (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death), CEREBROVASCULAR ACCIDENT (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death), COMA (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death), BLADDER SPHINCTER ATONY (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death), ACUTE KIDNEY INJURY (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death), SEPTIC SHOCK (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death) and APHASIA (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death). The patient died on 27-Jan-2022. The reported cause of death was Shock septic. An autopsy was not performed.	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 21-Jan-2022, Angiogram cerebral: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, Blood gases: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, Blood test: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, CSF culture: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, Chest X-ray: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, Computerised tomogram head: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, Echocardiogram: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, Electrocardiogram: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, Electroencephalogram: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, Physical examination: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, SARS-CoV-2 test negative: inconclusive (Inconclusive) Inconclusive. On 22-Jan-2022, Blood culture: inconclusive (Inconclusive) Inconclusive. On 22-Jan-2022, Tracheal aspirate culture: inconclusive (Inconclusive) Inconclusive. On 25-Jan-2022, Specialist consultation: inconclusive (Inconclusive) Inconclusive. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Treatment medication were not reported. Company comment: This regulatory case concerns an 87-year-old elderly male patient with medical history of COPD, hypertension arterial, renal failure chronic, neurocognitive deficit, and interchange of vaccine products (two doses of Comirnaty Covid19 vaccine), experienced the unexpected Fatal events Respiratory failure, Pneumonia, Cerebrovascular accident, Coma, bladder sphincter atony, Acute kidney injury, Septic shock, and Aphasia, one month twenty-nine days after a dose of mRNA-1273. The cause of death was reported as Septic shock. Autopsy was not performed. Advanced age of the patient could be a risk factor. Medical history of COPD, hypertension arterial, renal failure chronic could be confounding. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting.	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							Most recent FOLLOW-UP information incorporated above includes: On 22-Feb-2022: Added patient's medical history, lab data, concomitant medications, events (bilateral pneumonia, stroke, coma, bladder sphincter atony, renal failure acute, aphasia), updated seriousness, verbatim for events (respiration failure, septic shock) and deleted event (sopor). On 07-Mar-2022: Non-significant follow up appended, Senders comment updated	
[redacted]	TAIWAN, PROVINCE OF CHINA	Cold sweat, Presyncope	84.00	Male	Hypertension(C); Diabetes mellitus(C)	0	This regulatory authority case was reported by an other health care professional and describes the occurrence of PRESYNCOPE (Near-syncope, cold sweating) and COLD SWEAT (Near-syncope, cold sweating) in an 84-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Hypertension and Diabetes. On 29-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 30-Jan-2022, the patient experienced PRESYNCOPE (Near-syncope, cold sweating) (seriousness criterion death) and COLD SWEAT (Near-syncope, cold sweating) (seriousness criterion death). The patient died on 30-Jan-2022. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 30-Jan-2022, Blood pressure measurement: 178/81 mmhg 178/81 mmHg at 07:50, 80/53 mmhg 80/53 mmHg at 7:26 and 105/51 mmhg 105/51 mmHg at 09:39. On 30-Jan-2022, Electrocardiogram: showed asystole showed asystole at 18:11. On 30-Jan-2022, Heart rate: 52 bpm 52 BPM at 7:26 and 50 bpm 50 BPM at 09:39. On 30-Jan-2022, Oxygen saturation: 100% 100% at 7:26 and 100% 100% at 09:39. On 30-Jan-2022, Respiratory rate: 18 times/min 18 times/min at 7:26 and 20 times/min 20 times/min at 09:39. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant medication was not provided. On 30-Jan-2022, the patient sought medical attention at the ER and complained of shortness of breath. The patient's family expressed that the patient suddenly limped when waking up in the morning and walking. The patient had clear consciousness but was unable to describe discomfort.. At 7:26 GCS was E4V5M6, pain score as 0 point. At 7:50, the patient had cold sweats, difference in blood pressure in both arms. The doctor suggested that the patient receive computed tomography and blood test. At	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							09:39, patient's consciousness changed and GCS was E1V2M4. At 18:11 doctor announced that the heartbeat stopped. Cc: This Regulatory Authority case concerns a 84-year-old, male patient with relevant medical history of hypertension and diabetes, who experienced the unexpected fatal events of Presyncope and Cold Sweating. The events occurred approximately 1 day after the third dose of mRNA-1273 (Moderna covid-19 vaccine). The patient presented to the emergency department 1 day post vaccination with a complaint of shortness of breath. His physiological tests were pulse:52 bpm; respiration:18 beats/min; right arm blood pressure:80/53mmHg; oxygen saturation: 100%; pain index: 0 point; about 30min after, patient experienced cold sweats, decreased blood pressure in both arms. The physician recommended that the patient undergo CT and blood test (no results provided). Cardiac consult discussed treatment regimen, but family member declined surgery and signed a DNR. ECG showed asystole and the emergency physician announced that the patient had cardiac arrest (not reported as event by RA). However, this patient's multiple underlying medical conditions and advanced age remains a confounder. The benefit-risk relationship of mRNA-1273 (Moderna covid-19 vaccine) is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow-up received and had no new information	
[redacted]	TAIWAN, PROVINCE OF CHINA	Cardiac arrest	78.00	Female	Atrial fibrillation(C); Hypertensive heart disease(C)	0	This regulatory authority case was reported by an other health care professional and describes the occurrence of CARDIAC ARREST (Out of hospital cardiac arrest) in a 78-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Atrial fibrillation and Hypertensive heart disease (HCVD). On 27-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 02-Feb-2022, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced CARDIAC ARREST (Out of hospital cardiac arrest) (seriousness criterion death). It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product usage was not provided. Patient had blood type O. The patient received two doses of AZ's vaccine on June 24 and September 27, 2021. The family member said the patient fainted suddenly after going to the toilet, and found no breath or heartbeat, so 119 was called,	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							GCS: E1V1M1, cold limbs; skin: intact; tube on body: none; rupillary reaction: both eyes 5mm (-), chest press ongoing. The patient was examined and was sent to the Emergency Room. Follow up information: On 02-Feb-2022, the patient was found fainted and unconscious at home after going to the toilet, and was sent to hospital, and died before arrival. The first aid failed, and the patient died. No further details regarding treatment medications were disclosed. Company comment: This case concerns a 78-year-old female patient with medical history of Atrial fibrillation and Hypertensive heart disease, who experienced serious unexpected event of Cardiac arrest which ended with fatal outcome. The event occurred 6 days after the patient had received the mRNA-1273 vaccine (as third dose, booster). Reportedly, the patient fainted suddenly after going to the toilet, and was found with no breath or heartbeat. The patient was examined and sent to the Emergency Room (ER), however, the first aid failed and the patient died before arrival to the ER. It remained unknown whether an autopsy was performed. The underlying medical history of Atrial fibrillation and Hypertensive heart disease, as well as the patient's elderly age, remain major confounding factors for the reported event. The rechallenge is not applicable since the patient died. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting. Having in mind that this patient received AstraZeneca COVID-19 Vaccine prior to vaccination with the company product, Interchange of vaccine products should have been considered in this specific case. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Non-significant follow-up received.	
[redacted]	TAIWAN, PROVINCE OF CHINA	Asthma, Muscular weakness	71.00	Female	Cerebrovascular accident(H); Muscular weakness(H); Diabetes mellitus(C); Hypertension(C); Hyperlipidaemia(C)	0	This regulatory authority case was reported by an other health care professional and describes the occurrence of ASTHMA (Respiratory asthma) and MUSCULAR WEAKNESS (Limb weakness) in a 71-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 072F21A_1110129) for COVID-19 vaccination. The patient's past medical history included Stroke and Weakness of limbs (The patient had a history of Left limb weakness). Concurrent medical conditions included Diabetes, Hypertension and Hyperlipidemia. On 21-Jan-2022, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 26-Jan-2022, the patient experienced ASTHMA (Respiratory asthma) (seriousness criterion death) and MUSCULAR WEAKNESS (Limb weakness) (seriousness criterion death). The	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							reported cause of death was respiratory asthma and limb weakness. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In January 2022, Blood glucose: 354 354 mg/dl. In January 2022, Blood pressure measurement: 226/112 226/112 mmHg. In January 2022, Body temperature: 37.1 37.1 degrees. In January 2022, C-reactive protein: elevated Elevated. In January 2022, Chest X-ray: bilateral pneumonia Bilateral pneumonia. In January 2022, Echocardiogram: 56% of cardiac output, valvular insufficiency 56% of cardiac output, valvular insufficiency. In January 2022, Electrocardiogram: st segment abnormality ST segment abnormality. In January 2022, Heart rate: 119 119 BPM. In January 2022, Respiratory rate: 23 23 times/min. In January 2022, SARS-CoV-2 test: negative (Negative) Negative. In January 2022, White blood cell count: elevated Elevated. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. WWID was reported as [redacted] No concomitant medication information was reported Patient went for consultations and treatments and there was no problem concerning falling, home environment safety and living alone. The patient got up in the morning and went to the toilet and found that left weakness and respiratory asthma occurred. The patient went to the emergency department for treatment. On 29-Jan-2022 family member carried out discussions and decided to take the patient back to home before the patient was dead. On 26-Jan, the patient was sent to the emergency department for consultations and treatments due to cough, phlegm, dyspnea and general weakness. The patient was hospitalized for treatment. On 29-Jan, due to worsened respiratory failure, the family member refused first aid and voluntarily had the patient discharged and returned home. No treatment medication information was reported. Company Comment :This is a fatal case from Regulatory Authority that concerns a 71-year-old female patient, with medical history of stroke and weakness of limbs, who experienced the unexpected serious (due to death) events of	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							ASTHMA and MUSCULAR WEAKNESS (reported as Limb weakness), 5 days after the first dose of mRNA-1273 vaccine. The reported cause of death was asthma and weakness of limb. As per narrative of the source document, five days after vaccination she consulted due to cough, phlegm, dyspnea, and general weakness. Elevated blood pressure and tachycardia were found. A negative COVID-19 PCR test was performed, and the patient received oxygen as treatment. A bilateral pneumonia was diagnosed, and a valvular insufficiency was observed in the echocardiography with a ST segment abnormality in the electrocardiogram. The patient was hospitalized for treatment, but after three days the family refused first aid due to worsened respiratory failure and voluntary had the patient discharged and returned home and she died. The date of death w Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Significant follow-up contains additional events and updated I narrative.	
[redacted]	LATVIA	Acute myocardial infarction, COVID-19 immunisation, Sudden death	62.00	Male	Radical prostatectomy(H); Arteriosclerosis(H); Myocardial infarction(H)	0	This case was initially received via European Medicines Agency (Reference number[redacted] on 15-Feb-2022. The most recent information was received on 30-May-2022 and was forwarded to Moderna on 30-May-2022. This regulatory authority case was reported by a physician and describes the occurrence of SUDDEN DEATH (Sudden death) and ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction) in a 62-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 216036) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Radical prostatectomy in 2019, Atherosclerosis and Old myocardial infarction. On 10-Jan-2022 at 3:20 PM, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 10-Jan-2022 at 3:20 PM, the patient experienced COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine). On 25-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction) (seriousness criterion death). On 10-Jan-2022 at 3:20 PM, COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) outcome was unknown. The patient died on 24-Jan-2022. An autopsy was performed, but no results were provided. The autopsy-determined cause of death was Acute myocardial infarction. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant therapies and treatment details were not reported. Causal assessment of the event according to standardized causal assessment criteria of the World Health Organization and the Uppsala Monitoring Center is unlikely, as the direct cause of	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							death according to autopsy is acute transmural myocardial infarction and has been reported in patient with grade 3 atherosclerosis on the background of previous myocardial infarction. Company comment: This regulatory case from EMA concerns a 62-year-old, male patient, with the relevant medical history of radical prostatectomy, grade 3 atherosclerosis, & previous myocardial infarction, who experienced an unexpected, fatal events of an AESI Acute Myocardial infarction & an AESI Sudden death in association with a 3rd dose of mRNA-1273 vaccine. Patient reportedly expired after 2 weeks of vaccination. Cause of death per autopsy was reported as acute myocardial infarction. Details on the medical history, clinical course, diagnostics, further autopsy details, & treatments were not reported. Causal assessment of the event sudden death was unlikely per regulatory authority, as the direct cause of death according to autopsy was acute transmural myocardial infarction and has been associated in patient with grade 3 atherosclerosis on the background of previous myocardial infarction. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness assessed per Regulatory Authority reporting. Most recent FOLLOW-UP information incorporated above includes: On 30-May-2022: Significant follow-up: Added event, cause of death and sender's comment.	
[redacted]	AUSTRIA	Accident, Contusion, Craniocerebral injury, Haemorrhage intracranial, Pupil fixed, Subdural haemorrhage, Unresponsive to stimuli	81.00	Female	Fall(H); Hospitalisation(H) ; Contusion(H); Gait disturbance(H); COVID-19 VACCINE MODERNA; COVID-19 VACCINE MODERNA; COVID-19 VACCINE MODERNA; COVID-19 VACCINE MODERNA; COVID-19 VACCINE MODERNA; COVID-19 VACCINE MODERNA; COVID-19 VACCINE MODERNA; COVID-19 VACCINE MODERNA; COVID-19 VACCINE	NOVALGINA; PROTIFAR; CONCOR; FOLSAN; EXELON [RIVASTIGMINE]; XARELTO; DAFLON 1000; PANTOLOC; LASIX SPECIAL; ROSUMIBE [ROSUVASTATIN]; OLEOVIT [RETINOL]	This case was received via European Medicines Agency (Reference number: [redacted] on 16-Feb-2022 and was forwarded to Moderna on 16-Feb-2022. This regulatory authority case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PUPIL FIXED (pupils wide and light rigid), UNRESPONSIVE TO STIMULI (no longer available/no longer responsive), HAEMORRHAGE INTRACRANIAL (intracranial mass hemorrhage), ACCIDENT (accident, - was found lying on the ground), SUBDURAL HAEMORRHAGE (Traumatic subdural hemorrhage: without an open intracranial wound), CONTUSION (bruise of the knee) and CRANIOCEREBRAL INJURY (Circulated brain injury: without open intracranial wound) in an 81-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3004218) for COVID-19 vaccination. The patient's past medical history included Fall (Sturz) on 20-May-2021, Hospitalization (fall, hospitalized for several weeks) on 20-May-2021, Contusion (severe bruises) on 20-May-2021, Gait instability (gait uncertainty) on 20-May-2021, Escherichia coli infection (ESBL E. coli 3MRGN in urine) in July 2021, Condition aggravated (condition worsens more and more), Hallucination NOS, Inappetence, Activities of daily living impaired (There was a clear improvement in mobility and ADLs under physio and occupational therapy), Movements disturbance NOS (There was a clear improvement in mobility and ADLs under physio.- and occupational therapy), Memory impaired, Recurrent urinary tract infection (Rez. urinary tract infections),	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
					MODERNA; Hyperlipidaemia(C); Escherichia infection(H); Hepatic lesion(C); Atrial fibrillation(C); Hiatus hernia(C); Condition aggravated(H); Hallucination(H); Decreased appetite(H); Loss of personal independence in daily activities(H); Movement disorder(H); Wound infection staphylococcal(C); Hypoproteinaemia (C); Skin ulcer(C); Cognitive disorder(C); Goitre(C); Memory impairment(H); Cerebrovascular disorder(C); Cholelithiasis(C); Anticoagulant therapy; Urinary tract infection(H); Cardiac failure(C); Dementia(H); Cognitive disorder(C); Malaise(H); Peripheral venous disease(C); Hypertension(C); Tobacco abuse(H); Wound infection staphylococcal(H); Urinary tract infection bacterial(H); Nutritional condition abnormal(H); Cardiac failure(H); Hypothyroidism(C); Peripheral arterial occlusive disease(C);		Demented (suddenly completely dement), Feeling unwell, Nicotine abuse (z.n. Nicotine abuse), MRSA wound infection (MRSA detection in nose, throat and wounds (inner bone ulcers bds.)) in June 2021, Urinary tract infection bacterial (ESBL E. coli 3MRGN in urine) in July 2021, Nutritional condition abnormal (Reduced EZ), Decompensation cardiac (heart failure with recurrent cardiac decompensations), Sarcopenia (Sarcopenia/severely fall at risk) and Anticoagulant therapy (blood thinning drugs atrial fibrillation (DOAK)) since an unknown date. Previously administered products included for Product used for unknown indication: COVID-19 VACCINE MODERNA (Moderna LOT 3001531) on 16-Apr-2021, COVID-19 VACCINE MODERNA on 16-Apr-2021, COVID-19 VACCINE MODERNA on 16-Apr-2021, COVID-19 VACCINE MODERNA on 16-Apr-2021, COVID-19 VACCINE MODERNA on 16-Apr-2021, COVID-19 VACCINE MODERNA on 16-Apr-2021, COVID-19 VACCINE MODERNA on 16-Apr-2021, COVID-19 VACCINE MODERNA on 16-Apr-2021, COVID-19 VACCINE MODERNA on 16-Apr-2021, COVID-19 Vaccine Moderna on 16-Apr-2021, COVID-19 Vaccine Moderna on 16-Apr-2021, COVID-19 Vaccine Moderna on 16-Apr-2021, COVID-19 VACCINE MODERNA on 16-Apr-2021, COVID-19 Vaccine Moderna on 16-Apr-2021, COVID-19 Vaccine Moderna on 16-Apr-2021, COVID-19 VACCINE MODERNA on 16-Apr-2021 and COVID-19 VACCINE MODERNA on 16-Apr-2021. Past adverse reactions to the above products included Activities of daily living impaired with COVID-19 VACCINE MODERNA; Condition aggravated with COVID-19 VACCINE MODERNA; Contusion with COVID-19 Vaccine Moderna; Demented with COVID-19 Vaccine Moderna; Escherichia coli infection with COVID-19 VACCINE MODERNA; Fall with COVID-19 Vaccine Moderna; Feeling unwell with COVID-19 Vaccine Moderna; Gait instability with COVID-19 VACCINE MODERNA; Hallucination with COVID-19 Vaccine Moderna; Inappetence with COVID-19 VACCINE MODERNA; Infection MRSA with COVID-19 VACCINE MODERNA; MRSA wound infection with COVID-19 VACCINE MODERNA; Memory impaired with COVID-19 VACCINE MODERNA; Movements disturbance NOS with COVID-19 VACCINE MODERNA; Neurocognitive deficit with COVID-19 VACCINE MODERNA; Nutritional condition abnormal with COVID-19 VACCINE MODERNA; Sarcopenia with COVID-19 VACCINE MODERNA; and Urinary tract infection bacterial with COVID-19 VACCINE MODERNA. Concurrent medical conditions included Hyperlipidaemia (hyperlipidemia), Hepatic lesion (cystoid liver lesion), Atrial fibrillation (atrial fibrillation (DOAK)), Hernia hiatal (Hiatushernie), MRSA wound infection (MRSA - Colonation of Chron Ulc. Inner bone (ankle) (eradication 09-10-2021)), Hypoproteinaemia (protein deficiency), Ulcus cruris (open leg veins Ulcera crur. chron. mall. med. bilateral (left healed for several years)), Neurocognitive deficit (moderate neurocognitive	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
					Staphylococcal infection(C); Hip arthroplasty(C); Renal hamartoma(C); Chronic kidney disease(C); Sarcopenia(H); Chronic gastritis(C); COVID-19 VACCINE MODERNA; COVID-19 VACCINE MODERNA; COVID-19 VACCINE MODERNA; COVID-19 VACCINE MODERNA; COVID-19 VACCINE MODERNA; COVID-19 VACCINE MODERNA; COVID-19 VACCINE MODERNA; COVID-19 VACCINE MODERNA; COVID-19 VACCINE MODERNA; COVID-19 VACCINE MODERNA; Goitre(C)		impairment, 18/30 MMSE from 7/2021), Struma nodosa (Struma nodosa li.), Cerebral vascular disturbance (cAVK), Cholecystolithiasis (Cholecystolithiasis), Cardiac insufficiency (heart failure with recurrent cardiac decompensations), Neurocognitive deficit (moderate neurocognitive impairment, 18/30 MMSE from 7/2021), Chronic venous insufficiency (Chronic venous insufficiency), Hypertension arterial (Arterial hypertension), Latent hypothyroidism (latent hypothyroidism), Peripheral arterial occlusive disease (PAvK), Infection MRSA (MRSA detection in nose, throat and wounds (inner bone ulcers bds.)) since June 2021, Hip prosthesis insertion (z.n. hip tep), Kidney angiomyolipoma (Angiomyolipom re. Niere), Chronic renal insufficiency (Chronic renal failure), Chronic antral gastritis (chronic antral gastritis) and Goiter (left goiter). Concomitant products included METAMIZOLE SODIUM (NOVALGINA), CARBOHYDRATES NOS, LIPIDS NOS, MINERALS NOS, PROTEINS NOS (PROTIFAR), BISOPROLOL FUMARATE (CONCOR), FOLIC ACID (FOLSAN), RIVASTIGMINE (EXELON [RIVASTIGMINE]), RIVAROXABAN (XARELTO), DIOSMIN, HESPERIDIN (DAFLON 1000), PANTOPRAZOLE SODIUM SESQUIHYDRATE (PANTOLOC), FUROSEMIDE (LASIX SPECIAL), ROSUVASTATIN (ROSUMIBE [ROSUVASTATIN]) and RETINOL (OLEOVIT [RETINOL]) for an unknown indication. On 23-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 08-Oct-2021, the patient experienced PUPIL FIXED (pupils wide and light rigid) (seriousness criteria hospitalization and medically significant), UNRESPONSIVE TO STIMULI (no longer available/no longer responsive) (seriousness criteria hospitalization and medically significant), HAEMORRHAGE INTRACRANIAL (intracranial mass hemorrhage) (seriousness criteria death, hospitalization and medically significant), ACCIDENT (accident, - was found lying on the ground) (seriousness criterion hospitalization), SUBDURAL HAEMORRHAGE (Traumatic subdural hemorrhage: without an open intracranial wound) (seriousness criteria hospitalization and medically significant), CONTUSION (bruise of the knee) (seriousness criterion hospitalization) and CRANIOCEREBRAL INJURY (Circulated brain injury: without open intracranial wound) (seriousness criteria hospitalization and medically significant). The patient died on 09-Oct-2021. It is unknown if an autopsy was performed. At the time of death, PUPIL FIXED (pupils wide and light rigid), UNRESPONSIVE TO STIMULI (no longer available/no longer responsive), ACCIDENT (accident, - was found lying on the ground), SUBDURAL HAEMORRHAGE (Traumatic subdural hemorrhage: without an open intracranial wound), CONTUSION (bruise of the knee) and CRANIOCEREBRAL INJURY (Circulated brain injury: without open intracranial wound) had not resolved.	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In July 2021, Mini mental status examination: 18/30 18/30. On 29-Jul-2021, Blood albumin (35-52): 31.80 gl (Low) 31.80 gl. On 29-Jul-2021, Blood alkaline phosphatase (35-104): 151 u/l (High) 151 U/l. On 29-Jul-2021, C-reactive protein (0.0-5.0): 14.6 mg/l (High) 14.6 mg/l. On 29-Jul-2021, CSF red blood cell count (4.00-5.00): 3.88 t/l (Low) 3.88 T/l. On 29-Jul-2021, Eosinophil count (1.0-4.0): 4.6 % (High) 4.6 %. On 29-Jul-2021, Gamma-glutamyltransferase (0-35): 112 u/l (High) 112 U/l. On 29-Jul-2021, Haematocrit (38.0-44.0): 35.0% (Low) 35.0%. On 29-Jul-2021, Haemoglobin (12.0-16.0): 10.8 g/dl (Low) 10.8 g/dl. On 29-Jul-2021, Lymphocyte count (20.0-40.0): 19.4% (Low) 19.4%. On 29-Jul-2021, Platelet count (150-360): 370 g/l (High) 370 G/L. On 08-Sep-2021, SARS-CoV-2 test: negative (Negative) negatively. On 07-Oct-2021, SARS-CoV-2 test: negative (Negative) negatively. On 08-Oct-2021, Coma scale: at 4 (abnormal) at 4,The CCT showed mass intr	
[redacted]	NORWAY	Atrial fibrillation, Cardiac failure, COVID-19 immunisation, Endotracheal intubation, Renal failure, Respiratory failure, Staphylococcal sepsis, Tachycardia	71.00	Male	Chronic kidney disease(H); Chronic obstructive pulmonary disease(H); Cardiac failure(H); Emphysema(H); Plasma cell myeloma(H); Comirnaty; Comirnaty	DARATUMUMAB; BORTEZOMIB; DEXAMETHASONE	This case was received via European Medicines Agency (Reference number: [redacted] on 17-Feb-2022 and was forwarded to Moderna on 17-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of STAPHYLOCOCCAL SEPSIS (Staphylococcal sepsis), ATRIAL FIBRILLATION (Atrial fibrillation), ENDOTRACHEAL INTUBATION (Intubation NOS), RESPIRATORY FAILURE (Respiratory failure), TACHYCARDIA (Tachycardia), CARDIAC FAILURE (Cardiac failure aggravated) and RENAL FAILURE (Renal failure aggravated) in a 71-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Chronic renal failure, COPD, Heart failure, Emphysema and Myelomatosis (Immunosuppressed with daratumumab + bortezomib (Velcade) + dexamethasone, due to multiple myeloma.). Previously administered products included for Vaccination: Comirnaty and Comirnaty. Past adverse reactions to the above products included No adverse event with Comirnaty and Comirnaty. Concomitant products included DARATUMUMAB, BORTEZOMIB and DEXAMETHASONE for Myelomatosis. On 04-Oct-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 09-Oct-2021, the patient experienced ATRIAL FIBRILLATION (Atrial	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							fibrillation) (seriousness criterion death), ENDOTRACHEAL INTUBATION (Intubation NOS) (seriousness criterion death), RESPIRATORY FAILURE (Respiratory failure) (seriousness criterion death), TACHYCARDIA (Tachycardia) (seriousness criterion death) and RENAL FAILURE (Renal failure aggravated) (seriousness criterion death). On an unknown date, the patient experienced STAPHYLOCOCCAL SEPSIS (Staphylococcal sepsis) (seriousness criterion death), COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) and CARDIAC FAILURE (Cardiac failure aggravated) (seriousness criterion death). The patient died on 22-Oct-2021. It is unknown if an autopsy was performed. At the time of death, COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 09-Oct-2021, Echocardiogram: ejection fraction in the 20s. Ejection fraction in the 20s.. On 09-Oct-2021, X-ray: x-ray thorax found densification basal on the left X-ray thorax found densification basal on the left side.. On 10-Oct-2021, Echocardiogram: improvement of left ventricular function in sinus Improvement of left ventricular function in sinus rhythm. Left ventricular ejection fraction: 35-40 percent.. On 13-Oct-2021, Glomerular filtration rate: 17 17 millilitre per minute per 1.73 square metre. On 17-Oct-2021, Magnetic resonance imaging: mri caput noted two small point-shaped cerebral in MRI caput noted two small point-shaped cerebral infarctions, one of which with a slight connected subarachnoidal hematoma. This could not explain the comatose state.. On 22-Oct-2021, Body temperature: 40 40 degree Celsius. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered STAPHYLOCOCCAL SEPSIS (Staphylococcal sepsis), ATRIAL FIBRILLATION (Atrial fibrillation), ENDOTRACHEAL INTUBATION (Intubation NOS), RESPIRATORY FAILURE (Respiratory failure), TACHYCARDIA (Tachycardia), CARDIAC FAILURE (Cardiac failure aggravated) and RENAL FAILURE (Renal failure aggravated) to be possibly related. No further causality assessment was provided for COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine). No treatment medication details were provided. Company comment: This regulatory authority case concerns a 71-year-old male patient, with relevant medical history of myelomatosis under immunosuppressed treatment, heart failure, COPD, emphysema and CRF, who experienced the fatal AESI of respiratory, cardiac and renal failure, atrial fibrillation and serious (death) unexpected events of staphylococcal sepsis, tachycardia and endotracheal	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							intubation after the third dose of mRNA-1273. It was reported that the patient was hospitalized due to clinical pulmonary edema, respiratory failure and kidney failure (aggravated) 6 days after receiving the mRNA-1273 vaccine. Then, the patient was intubated due to respiratory failure, electrical cardioversion was reported. The patient did not responded to repeated awakening attempts and developed a Staphylococcal sepsis. The patient died 19 days after the third dose of mRNA-1273. No information regarding if an autopsy was performed. Cause of death was not further specified. Patient's underlying diseases remain contributing factors. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	
[redacted]	FRANCE	Tachycardia	61.00	Female	Overweight(C); Type 2 diabetes mellitus(C)	ACEBUTOLOL	This case was initially received via European Medicines Agency (Reference number: [redacted] on 17-Feb-2022. The most recent information was received on 04-Mar-2022 and was forwarded to Moderna on 04-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of TACHYCARDIA (Tachycardia) in a 61-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Concurrent medical conditions included Overweight and Type 2 diabetes mellitus. Concomitant products included ACEBUTOLOL for an unknown indication. On 22-Oct-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 30-Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced TACHYCARDIA (Tachycardia) (seriousness criterion death). The patient died on 30-Oct-2021. The reported cause of death was cardiopulmonary arrest. An autopsy was not performed. mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on 22-Oct-2021. No Treatment information was provided. Dosage Text: R1 Company comment: This is a regulatory case concerning a 61-year-old female patient with medical history of Overweight, Type 2 diabetes mellitus and concomitant medication Acebutolol which suggests possible underlying arrhythmia or cardiovascular disease, who experienced death with the Fatal unexpected, event of tachycardia, which occurred 8 days after a dose of mRNA-1273 vaccine. The patient died on 30-Dec-2021. The reported cause of death was cardiopulmonary arrest. An autopsy was not performed. The mentioned medical history remains a confounder for the event. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							Most recent FOLLOW-UP information incorporated above includes: On 04-Mar-2022: Significant follow-up received Autopsy was not performed and cause of death was updated.	
[redacted]	FRANCE	COVID-19 pneumonia, Vaccination failure	89.00	Male	Aortic aneurysm(H); Coronary arterial stent insertion; Carotid arteriosclerosis(H); Hypertension(H); Myocardial infarction(H); Cardiac assistance device user(H); Atrial fibrillation(H); Nicotine dependence(C)	KARDEGIC; LOVENOX HP; PANTOPRAZOLE; BISOCE; FINASTERIDE; TAHOR	This case was received via European Medicines Agency (Reference number: [redacted] on 17-Feb-2022 and was forwarded to Moderna on 17-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of COVID-19 PNEUMONIA (SARS-CoV-2 pneumonia) and VACCINATION FAILURE (Vaccination failure) in an 89-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004834) for COVID-19 vaccination. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 vaccination. The patient's past medical history included Aneurysm of aorta, Carotid artery atheroma, Hypertension arterial, Infarct myocardial in 2017, Artificial cardiac pacemaker wearer in 2015, AFib and Coronary arterial stent insertion in 2017. Concurrent medical conditions included Tabaquism. Concomitant products included FINASTERIDE for Disorder urinary tract, PANTOPRAZOLE for Gastritis prophylaxis, BISOPROLOL FUMARATE (BISOCE) for Hypertension arterial, ACETYLSALICYLATE LYSINE (KARDEGIC) and ATORVASTATIN CALCIUM (TAHOR) for Prevention, ENOXAPARIN SODIUM (LOVENOX HP) for Thromboembolism prophylaxis. On 06-Mar-2021, the patient received dose of TOZINAMERAN (COMIRNATY) (Intramuscular) 2 dosage form. On 01-Apr-2021, received dose of TOZINAMERAN (COMIRNATY) (Intramuscular) dosage was changed to 2 dosage form. On 29-Sep-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 07-Jan-2022, the patient experienced COVID-19 PNEUMONIA (SARS-CoV-2 pneumonia) (seriousness criteria death and hospitalization) and VACCINATION FAILURE (Vaccination failure) (seriousness criteria death and hospitalization). The patient died on 15-Jan-2022. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No treatment information was provided. Company comment: This Fatal Regulatory Authority case concerns a 89-year-old, male patient, with medical history of tabaquism, hypertension, atrial fibrillation and myocardial infarction, who experienced the unexpected, serious (death/hospitalization) and AESI of COVID-19 pneumonia. Vaccination failure was also reported, however,	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							the patient received previously as first and second dose of his COVID-19 vaccination schedule two doses of Cominarty's COVID-19 vaccine. The event occurred 3 months and 9 days after receiving a dose of mRNA-1273 vaccine, reported as R1 and he died 8 days after. Cause of death was not reported. Autopsy report is not available. Patient's age, gender, medical history of tabaquism, hypertension, atrial fibrillation and myocardial infarction remain as confounders. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.	
[redacted]	JAPAN	Blood pressure decreased, Cardio-respiratory arrest, Dehydration, Diarrhoea, Gastroenteritis, Loss of consciousness, Pneumonia aspiration, Pyrexia, Vomiting	42.00	Male	Epilepsy(C); Intellectual disability(C); Constipation(C); Infectious pleural effusion(C); COMIRNATY; COMIRNATY	0	This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 16-Feb-2022. The most recent information was received on 11-Mar-2022 and was forwarded to Moderna on 17-Mar-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a (physician), was received via the PMDA (Ref: [redacted] [redacted] On 11-Mar-2022, follow-up information was received from a physician. Childhood epileptic seizure was controlled by treatment with oral treatment. The patient made regular visits to the psychiatric department of the reporting hospital for profound intellectual disability. On 01-Jul-2021, the patient received the 1st dose of coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 29-Jul-2021, the patient received the 2nd dose of coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, body temperature before the vaccination: 35.9 degrees Celsius. On 10-Feb-2022, at 14:00, the patient received the 3rd vaccination with this vaccine. There was no particular problem after the vaccination. On 11-Feb-2022, from the morning, the patient had frequent watery stools. The patient vomited several times from the night to before dawn on 12-Feb-2022. On 12-Feb-2021, before dawn, after vomiting, pyrexia developed with choking. At 09:30, the patient visited the reporting hospital. Pyrexia of 38.7 degrees Celsius was noted, SpO2 was 97%, RR was 20/min, and crackles were noted in the right lung field. Blood pressure was unmeasurable, radial A was palpable feebly, HR was 110-140, and the patient was awake. Administration of glucose lactated ringer's solution 500 mL was performed. Although videoendoscopic evaluation of swallowing (VE) showed no obvious aspiration, there was mild cough. In addition to severe dehydration and decreased blood pressure due to gastroenteritis, pneumonia aspiration due to vomiting was suspected, and the patient was taken to another hospital by ambulance. During transportation, the patient vomited heavily and lost consciousness. Although ambulance workers performed cardiopulmonary resuscitation, on arrival at the hospital, the patient was in a state of cardio-respiratory arrest. Endotracheal intubation was performed. The tubes were also covered by vomit. Cardiotonic drugs were administered, but there was no response, and the patient was confirmed dead. No autopsy was performed. The cause of death was an unknown intrinsic factor. The outcome of pyrexia, gastroenteritis, blood pressure decreased, suspected aspiration pneumonia, and loss of consciousness was unknown. The outcome of diarrhea, vomiting, severe dehydration, and cardio-respiratory was reported as fatal. No follow-up investigation will be made. Reporter comments continuation:	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							Since this event developed from the next day of the vaccination, the occurrence of the adverse events is temporally related to timing of administration of this vaccine. The patient had taken concomitant drugs for a long time before the vaccination with this vaccine, so the occurrence of adverse events is not related to concomitant drugs. Because bowel movement disturbance may have been related to the occurrence of adverse events, the occurrence of adverse events is related to pathogenic factors of bowel movement disease. It is difficult to determine whether the adverse events of diarrhea and vomiting were caused by the vaccination with this vaccine. Bowel movement disturbance was present before the vaccination. Regarding death, the patient had mild cough although history of left pyothorax and subsequent videoendoscopic evaluation of swallowing (VE) showed no apparent aspiration, and there may have been latent decreased swallowing function. Follow-up received on 11-MAR-2022 Updated: Patient Information, Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments Company Comment: Although dehydration developed after the administration of ELASOMERAN, influence of contingent event can also be considered.	
[redacted]	JAPAN	Altered state of consciousness, Cerebral infarction, Heat illness, Movement disorder, Multiple organ dysfunction syndrome, Shock	76.00	Male	COMIRNATY; COMIRNATY; Diabetes mellitus(C); Atrial fibrillation(C)	0	This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 16-Feb-2022. The most recent information was received on 16-Mar-2022 and was forwarded to Moderna on 24-Mar-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, [redacted]. On 16-Mar-2022, follow-up information was received from a physician. On an unknown date, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 12-Feb-2022, the patient received the 3rd vaccination with this vaccine. On 13-Feb-2022, around 16:00, consciousness disturbed developed. The patient was found collapsed and was transported by ambulance. The patient was suspected to have developed heat illness in a hot environment due to difficulty moving due to an unforeseen accident or a preceding disease. The patient was already in multi-organ failure, in shock, and difficult to save the patients life. CT showed the possibility of multiple cerebral infarctions but could not be confirmed. There was a suspected cerebral infarction due to chronic atrial fibrillation. On 14-Feb-2022, the patient was confirmed dead. The cause of death was heat illness. No autopsy was performed. The outcome of consciousness disturbed, possible multiple cerebral infarctions, difficulty in moving, suspected heat illness, multi-organ failure and shock was reported as fatal. No follow-up investigation will be made. Reporter's comment: The causal relationship between the progress and this vaccination is unknown. There is a possibility that cerebral infarction caused the difficulty in moving, resulting in heat illness, but the possibilities that the cause was atrial	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							fibrillation, that the cerebral infarction was a result rather than a cause, and that the patient had no cerebral infarction from the beginning were also cannot be ruled out. Other factors include the possibility of suspected cerebral infarction due to chronic atrial fibrillation. The relationship between cause of death and adverse events is unknown. The cause of the heat illness was a fall in a bedrock bath facility, which may have been caused by cerebral infarction. Since it cannot be denied that cerebral infarction may be caused by thrombosis or chronic atrial fibrillation due to vaccination with this vaccine, it is unclear whether the occurrence of adverse events is temporally related to the timing of administration of this vaccine. The occurrence of adverse events may be associated with pathological factors of chronic atrial fibrillation. Neither the presence or absence of cerebral infarction nor the association of cerebral infarction with this vaccination, if any, can be determined. Follow-up received on 16-MAR-2022 Updated: Patient Information, Other Relevant History, Lab Data, Event Information, Narrative, Reporter Comments LP Company Comment: As for heat illness, the event developed after the administration of ELASOMERAN, but it could also be due to the patient's environment, or other influences. As for cerebral infarction, the event developed after the administration of ELASOMERAN, but it could also be due to the patient's medical history or concurrent events, or other influences. Company comment: This spontaneous case concerns a 76-year-old, male patient with medical history of Diabetes mellitus and Atrial fibrillation, who experienced unexpected serious events of Cerebral infarction (seriousness criterion: Fatal, Hospitalisation, Medically significant), Heat illness (seriousness criterion: Fatal, Hospitalisation, Medically significant), Multiple organ dysfunction syndrome (seriousness criterion: Fatal, Medically significant), Shock (seriousness criterion: Fatal, Medically significant), Movement disorder (seriousness criterion: Fatal, Hospitalization) and Altered state of consciousness (seriousness criterion: Fatal, Hospitalisation, Medically significant). It was reported that a day after receiving the mRNA-1273 vaccine (as third dose), the patient developed disturbed consciousness. The patient was found collapsed and was transported by ambulance. The patient was suspected to had developed heat illness in a hot environment due to difficulty moving due to an unforeseen accident or a preceding disease. The patient was already in multi-organ failure and shock. CT showed the possibility of multiple cerebral infarctions due to chronic atrial fibrillation, but it could not be confirmed. The cause of death was heat illness and no autopsy was performed. The outcome of consciousness disturbed, possible multiple cerebral infarctions, difficulty in moving, suspected heat illness, multi-organ failure and shock was reported as fatal. Underlying medical history of atrial fibrillation remains a major confounder for Cerebral infarction which could contribute to movement disorder and altered state of consciousness. The	

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							patient's elderly age remains an additional confounder. Having in mind that this patient received Comrinaty vaccine prior to vaccination with the company product, Interchange of vaccine products should have been considered in this specific case. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.	
[redacted]	ITALY	Anuria, Multiple organ dysfunction syndrome, Septic shock	74.00	Male	Respiratory failure(H); Amnestic disorder(H); Ex-tobacco user(H); Diabetic retinopathy(C); Sepsis(H); Diaphragmatic hernia(H); Peripheral arterial occlusive disease(H); Aortic valve replacement(H); Lactic acidosis(H); Hypertensive heart disease(H); Anaemia(H); Insulin-requiring type 2 diabetes mellitus(C); Hypertension(C); Hyperuricaemia(H); Atrial fibrillation(C); Hepatic steatosis(H); Acute pulmonary oedema(H); Cerebral infarction(H); Femur fracture(H); COMIRNATY; COMIRNATY	TOUJEO; TORVAST; CARDIOASPIRIN; LANOXIN; ELIQUIS; LASIX P; SERTRALINE; KANRENOL; SEQUACOR; LANSOX; NOVORAPID	This case was initially received via European Medicines Agency (Reference number [redacted] on 17-Feb-2022. The most recent information was received on 07-Mar-2022 and was forwarded to Moderna on 07-Mar-2022. This regulatory authority case was reported by a physician and describes the occurrence of ANURIA (anuria, urinary septic shock with MOF, cardiopathic, diabetic, AOCP), MULTIPLE ORGAN DYSFUNCTION SYNDROME (anuria, urinary septic shock with MOF, cardiopathic, diabetic, AOCP) and SEPTIC SHOCK (anuria, urinary septic shock with MOF, cardiopathic, diabetic, AOCP) in a 74-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005887) for COVID-19 vaccination. The patient's past medical history included Respiration failure on 01-Nov-2015, Amnestic disorder, Recovered smoker (end date-01-Jan-1992), Septicaemia (01/10/2021: admitted again for septicemia) on 01-Jan-2020, Diaphragmatic hernia, Obstructive arteriosclerosis of lower extremities on 01-Sep-2021, Aortic valve replacement, Lactic acidosis (iatrogenic) on 01-Aug-2015, Hypertensive heart disease, Anemia (severe enteric loss anemia) on 01-Aug-2015, Hyperuricaemia, Hepatic steatosis on 01-Jan-2010, Acute pulmonary oedema on 01-Jan-2007, Cerebral infarct on 01-Jan-2007 and Femur fracture (dx) on 01-Jan-1972. Previously administered products included for SARS-CoV-2 immunisation: COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03) on 06-Apr-2021 and COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03) on 27-Apr-2021. Past adverse reactions to the above products included No adverse event with COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03) and COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03). Concurrent medical conditions included Diabetic retinopathy, Insulin-requiring type 2 diabetes mellitus on 01-Jan-2007, Hypertension arterial and Atrial fibrillation. Concomitant products included INSULIN GLARGINE (TOUJEO), ATORVASTATIN CALCIUM (TORVAST), ACETYLSALICYLIC ACID (CARDIOASPIRIN), DIGOXIN (LANOXIN), APIXABAN (ELIQUIS), FUROSEMIDE (LASIX P), SERTRALINE, POTASSIUM CANRENOATE (KANRENOL), BISOPROLOL FUMARATE (SEQUACOR), LANSOPRAZOLE (LANSOX) and INSULIN ASPART (NOVORAPID) for an unknown indication. On 22-Nov-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On 30-Jan-2022, the patient experienced ANURIA (anuria, urinary septic shock with	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							MOF, cardiopathic, diabetic, AOCP) (seriousness criterion death), MULTIPLE ORGAN DYSFUNCTION SYNDROME (anuria, urinary septic shock with MOF, cardiopathic, diabetic, AOCP) (seriousness criterion death) and SEPTIC SHOCK (anuria, urinary septic shock with MOF, cardiopathic, diabetic, AOCP) (seriousness criterion death). The patient died on 10-Feb-2022. The reported cause of death was Shock septic. An autopsy was not performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 30-Jan-2022, Blood test: inconclusive (Inconclusive) Inconclusive. On 30-Jan-2022, Chest X-ray: inconclusive (Inconclusive) Inconclusive. On 30-Jan-2022, SARS-CoV-2 test negative: inconclusive (Inconclusive) Inconclusive. On 30-Jan-2022, Vital signs measurement: inconclusive (Inconclusive) Inconclusive. On 31-Jan-2022, Blood gases: inconclusive (Inconclusive) Inconclusive. On an unknown date, Ultrasound scan: inconclusive (Inconclusive) Inconclusive. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Reporter states first dose on 06/04/2021 comirnaty vaccine lot: et7205 sc: 31/07/2021, the second dose on 27/04/2021 comirnaty vaccine lot: ex3599 sc: 31/08/2021. Concomitant pathologies includes diabetes mellitus, heart disease and aocp. Company Comment: This is a Regulatory case concerning a 74-year-old male patient with interchange of vaccine administration (COVID-19 vaccine, 2 doses of Comirnaty 6-7 months (interval of 21 days) prior to mRNA-1273 dose and medical history of Septicaemia (recurrence: 2020 & Oct 2021), Obstructive arteriosclerosis of lower extremities (2021), Aortic valve replacement, Severe enteric loss anemia (2015), Hepatic steatosis (2010), Hyperuricaemia, Acute pulmonary oedema (2007), Cerebral infarct (2007), and concurrent Type 2 diabetes mellitus (15y), Diabetic retinopathy, Hypertension arterial, Atrial fibrillation, Heart disease and AOCP. The patient experienced the serious fatal unexpected events of Anuria (AESI), Multiple Organ Dysfunction Syndrome and Septic shock. The events occurred approximately 2 months 9 days after a dose of mRNA-1273 received as the third dose for COVID-19 Vaccination. The patient died on 10-Feb-2022 (11 days after events onset). The reported cause of death was Shock septic. An autopsy was not performed. Diagnostic workup (Blood test, Chest X-ray, Vital signs, blood gases) was reported with inconclusive results, however an urinary origin of the septic shock was described. Treatment information was not provided. The increased risk of developing infections and sepsis due to type 2 diabetes remains a confounder. Suggestive	

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							urinary tract infection could be contributory for septic shock. Septic shock is a contributing cause of MODS and anuria. Patient's advanced age, vast comorbidities and heart disease remain as confounders and increase risk for fatal outcome. Moreover case could be confounded by polypharmacy. The benefit-risk relationship of COVID-19 Vaccine Moderna (mRNA-1273) is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 04-Mar-2022: Follow Up received with Non-Significant information. On 07-Mar-2022: Follow up received contains medical history, concomitant medications and event details.	
[redacted]	FRANCE	COVID-19 pneumonia, Vaccination failure	91.00	Male	Hypertension(H); Myocardial ischaemia(C); Coronary artery disease(C); Vascular device user(H); Atrial fibrillation(H); Colon cancer(H); Cardiac murmur(C); Hyperthyroidism(C); Benign prostatic hyperplasia(H)	PERINDOPRIL; ATENOLOL; DIFFU K; FINASTERIDE; RIVAROXABAN; ALFUZOSINE UNO; FUROSEMIDE	This case was initially received via European Medicines Agency (Reference number: [redacted] on 18-Feb-2022. The most recent information was received on 18-Feb-2022 and was forwarded to Moderna on an unknown date. This regulatory authority case was reported by a physician and describes the occurrence of COVID-19 PNEUMONIA (SARS-CoV-2 pneumonia) and VACCINATION FAILURE (Vaccination failure) in a 91-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 091F21A) for COVID-19 vaccination. Co-suspect product included non-company product COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) for SARS-CoV-2 vaccination. The patient's past medical history included Hypertension arterial, Coronary stent user, AFib, Colon cancer and Benign prostatic hyperplasia. Concurrent medical conditions included Ischaemic heart disease, Disease coronary artery, Systolic murmur and Hyperthyroidism. Concomitant products included ATENOLOL and RIVAROXABAN for AFib, FINASTERIDE and ALFUZOSIN HYDROCHLORIDE (ALFUZOSINE UNO) for Disorder urinary tract, PERINDOPRIL and FUROSEMIDE for Hypertension arterial, POTASSIUM CHLORIDE (DIFFU K) for Potassium supplementation. On 25-Mar-2021, the patient received first dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) (Intramuscular) 1 dosage form. On 16-Jul-2021, received second dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) (Intramuscular) dosage was changed to 1 dosage form. On 15-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced COVID-19 PNEUMONIA (SARS-CoV-2 pneumonia) (seriousness criteria death and hospitalization) and VACCINATION FAILURE (Vaccination failure) (seriousness criteria death and hospitalization). The patient died on 17-Jan-2022. It is unknown if an autopsy was performed.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No treatment drug was provided by reporter. COMPANY COMMENT : This is a regulatory authority case concerning a 91-year-old male patient with Hypertension arterial, Ischaemic heart disease, Disease coronary artery, Coronary stent user, AFib and Colon cancer, who had fatal outcome with unexpected serious AESI of COVID-19, which occurred on an unknown day after a dose of mRNA-1273 (third dose of COVID-19 vaccine; previous vaccination with Chadox1 NCOV-19 Aztrazeneca). Vaccination failure was captured as an event as per Regulatory Authority assessment. The patient died on 17-Jan-2022, one month and 2 days after receiving mRNA-1273. Clinical course and treatment details were not provided. It is unknown if an autopsy was performed. Patient's advanced age and medical conditions remains as confounder for the event and the fatal outcome. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 18-Feb-2022: Upon internal review on 24-Feb-2022, significant correction was performed. The seriousness criteria of the event SARS-CoV-2 pneumonia was updated. On 18-Feb-2022: Upon query received from business partner, non-significant correction was performed on 03-Mar-2022. The age and gender of patient was updated from 45-year-old female to 91-year-old male in company comment.	
[redacted]	FRANCE	Death	62.00	Male	Asthma(C)	0	This case was received via European Medicines Agency (Reference number: [redacted] on 18-Feb-2022 and was forwarded to Moderna on 18-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of DEATH (death of unknown cause) in a 62-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3006320) for COVID-19 vaccination. History of COVID-19: unknown PCR test history: unknown History of allergies: unknown. Concurrent medical conditions included Asthma. On 11-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. Death occurred on 29-Jan-2022 The patient died on 29-Jan-2022. The cause of death was not reported. An autopsy was not performed. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							Company comment: This is a fatal regulatory case concerning a 62-year-old male patient with Asthma and obesity (BMI 31.4), who experienced the serious unexpected event Death of unknown cause, 18 days after an unspecified dose of mRNA-1273. Very limited information has been provided regarding the event. The cause of death was not reported. An autopsy was not performed. Patient's medical conditions could be potential confounders. The benefit-risk relationship of mRNA-1273 is not affected by this report. Dosage text R1. Concomitant medications was not provided by the reporter. Treatment information was not provided.	
[redacted]	SWITZERLAND	Cerebral haemorrhage	71.00	Male	Hypertension(C); Coronary artery disease(C); Acute myocardial infarction(H); Peripheral arterial occlusive disease(C); Sleep apnoea syndrome(C); Hypercholesterolaemia(C); Gout(C)	TAMSULOSIN MEPHA; CANDESARTAN; ASPIRIN CARDIO; ROSUVASTATIN MEPHA LACTAB; PANTOPRAZOL SANDOZ	This regulatory authority case was reported by a consumer and describes the occurrence of CEREBRAL HAEMORRHAGE (Intracerebral haemorrhage) in a 71-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch nos. 3002917/ 3003606 and 3002917/ 3003606) for COVID-19 vaccination. The patient's past medical history included Non ST segment elevation myocardial infarction on 31-May-2018. Concurrent medical conditions included Arterial hypertension, Coronary heart disease, Peripheral arterial occlusive disease, Apnea syndrome, Hypercholesteraemia and Gout. Concomitant products included TAMSULOSIN HYDROCHLORIDE (TAMSULOSIN MEPHA), CANDESARTAN, ACETYLSALICYLIC ACID (ASPIRIN CARDIO), ROSUVASTATIN CALCIUM (ROSUVASTATIN MEPHA LACTAB) and PANTOPRAZOLE SODIUM SESQUIHYDRATE (PANTOPRAZOL SANDOZ) for an unknown indication. On 23-Jun-2021, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 28-Jul-2021, received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 12-Aug-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced CEREBRAL HAEMORRHAGE (Intracerebral haemorrhage) (seriousness criteria death, hospitalization, disability and life threatening). The patient died on 20-Aug-2021. It is unknown if an autopsy was performed. Patient was brought to the hospital via ambulance in case of aphaisa, vigilance reduction (GCS 10, over course 6) and hypertensive derailment. Patient had his second vaccine, lot number 3003606, was carried out on 28.07.21. On 12.08.21 Relevant findings: Skull CT: Extensive hypertensive mass hemorrhage in basal ganglia and frontal lobe on the left with	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							ventricle slump in all three ventricles and midline displacement. none demarked infarction areas, no aneurysm, no AVM. On 15.08.21 EEG: none epilepsy potentials, no status epilepticus. On 17.08.21 MRI: ICB left, demarked ischemia, mostly uncal hernia on the left. Diagnosis was Hypertensive basal ganglia hemorrhage in arterial hypertension. Patient was transfer to intensive care unit and single shot of mannitol was administrated, to stabilize Blood pressure and intracranial pressure with drug therapy. In case of persistent. On 17.08.2021 In case of persistently poor neurological status (GCS 7, none sedation), a treatment withdrawal occurred after a detailed consultation of relatives with the aim of organ donation after circulatory arrest in accordance with the suspected patient request. CC: This case concerns a 71-year-old male patient with relevant medical history of non-STEMI, hypertension, coronary artery disease, peripheral arterial occlusive disease and hypercholesterolemia, who experienced serious due to hospitalization, disability and life-threatening, unexpected AESI of cerebral haemorrhage. The event occurred approximately 15 days after the 2nd dose of the mRNA-1273. The patient was hospitalized due to aphasia, vigilance reduction with GCS 10 and hypertensive derailment. The CT showed hypertensive basal ganglia hemorrhage in arterial hypertension. Due to poor neurological status, treatment withdrawal was done and the patient passed away due to the event. The patient's relevant medical history aare possible confounders. The benefit-risk relationship of mRNA-1273 is not affected by this report.	
[redacted]	GERMANY	Cardiac arrest, Death	83.00	Male	Dementia(C); Cardiac failure(C); Myocardial infarction(H)	0	This case was received via European Medicines Agency (Reference number [redacted] on 22-Feb-2022 and was forwarded to Moderna on 22-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (cause of death unknown) and CARDIAC ARREST (cardiac arrest) in an 83-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 216046) for COVID-19 vaccination. Patients pre-existing diseases include heart failure, several myocardial infarctions progressive dementia/patient has been suffering from severe heart failure after multiple myocardial infarctions for years. Progressive dementia was also known. She cared for herself at home with support from nursing staff and was mobile in and around the house. The patient's past medical history included Infarct myocardial. Concurrent medical conditions included Dementia and Cardiac insufficiency. On 28-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 3 dosage form. On 29-Jan-2022, the patient experienced DEATH (cause of death unknown) (seriousness criterion death) and CARDIAC ARREST (cardiac arrest) (seriousness criterion death). The patient died on 29-Jan-2022. The cause of death was not reported. It is unknown if an autopsy was performed.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							Concomitant product use was not provided by the reporter. The family doctor performed the vaccination during a home visit and the patient died the following day while walking stairs in the garden because of cardiac arrest. Treatment information was not provided. Company comment: This regulatory authority case concerns a 83-year-old male patient with a relevant medical history of multiple Myocardial infarctions, Cardiac failure and Dementia, who experienced the fatal unexpected events of Cardiac arrest and Death (reported as unknown cause of death), approximately 1 day after receiving a dose mRNA- 1273 vaccine (reported as 3 dosage form) and had a fatal outcome on the same day. The patient died while walking stairs in the garden, as a result of cardiac arrest. Cause of death not further specified. It is unknown if an autopsy was performed. Patient's age and the mentioned medical history remain a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	
[redacted]	JAPAN	Dyspnoea, Interstitial lung disease, Pneumonia bacterial	91.00	Male	Hypertension(C); Interstitial lung disease(C); Cardiac failure chronic(C); Atrial fibrillation(C); Femur fracture(H)	PREDONINE-1; VASOLANDE; CARVEDILOL; FRANDOL S	This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 21-Feb-2022. The most recent information was received on 06-Apr-2022 and was forwarded to Moderna on 14-Apr-2022. This case was reported by a pharmacist via a medical representative. On 28-Feb-2022, follow-up information was received from a physician. On 06-Apr-2022, follow-up information was received from a physician. On 21-May-2021, the patient received the 1st dose of a COVID-19 vaccine (product name unknown). On 11-Jun-2021, the patient received the 2nd dose of a COVID-19 vaccine (product name unknown). On an unknown date, body temperature before the vaccination: 36.2 degrees Celsius. On 13-Feb-2022, at 11:00, the patient received the 3rd vaccination with this vaccine. On 16-Feb-2022, around 01:00, dyspnea developed. The patient became unable to move and thus was transported by ambulance. On arrival at the hospital, blood pressure was 142/96 with pulse of 150/min, and SaO2 of 93% (5 L of oxygen via a mask), and the patients consciousness was clear. Based on the results of the lung CT and blood test, exacerbation of interstitial pneumonia and complication of bacterial pneumonia were considered. For aggravation of respiratory status, steroid pulse therapy (methylprednisolone sodium succinate 500 mg) was concomitantly performed in addition to administration of antibiotics (meropenem hydrate). Oxygen was administered at 6 L via a mask. On 17-Feb-2022, the respiratory status gradually improved. Antibiotics (meropenem hydrate) and steroid therapy were continued. Around 20:00, the respiratory status was aggravated. Although 10 L of oxygen was administered via a reservoir mask, there was no improvement in SaO2, which was in the range of 70%. On 18-Feb-2022, the respiratory status gradually worsened. At 08:44, the patient died. The cause of death was pneumonia. No autopsy was performed. The outcome of dyspnea, bacterial pneumonia, and exacerbation	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							of interstitial pneumonia was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: Since exacerbation of interstitial pneumonia is possible, the occurrence of adverse events is associated with pathological factors of interstitial pneumonia and cardiac failure. Since interstitial pneumonia may have been aggravated by administration of this vaccine, there was a relationship between the cause of death and adverse events. Since dyspnea occurred within 3 days after vaccination with this vaccine, it is possible that the vaccine contributed to the exacerbation of interstitial pneumonia. Follow-up received on 28-FEB-2022 Updated: Reporter Information, Patient Information, Other Relevant History, Lab Data, Product Information, Event Information, Narrative Follow-up received on 06-APR-2022 Updated: Patient Information, Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments Company Comment: Interstitial lung disease developed after administration of ELASOMERAN, but it may also be affected by concurrent condition. Also, pneumonia bacterial developed after administration of ELASOMERAN, but it is possible that it was an incidental occurrence. Also, dyspnoea developed after administration of ELASOMERAN, but it may also be affected by intercurrent event.	
[redacted]	JAPAN	Cardiac failure, Death, Pallor	86.00	Male	Diabetes mellitus(C); Hypertension(C); Prostatism(C)	INSULIN	This case was received via Takeda Pharmaceuticals (Reference number [redacted] on 21-Feb-2022 and was forwarded to Moderna on 24-Feb-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by (a vaccination venue manager), was received via the PMDA (Ref, [redacted]. The patient was under treatment with oral medication for diabetes mellitus, hypertension, and prostatism, with concomitant use of insulin self-injection for diabetes mellitus. On an unknown date, the patient received the 1st dose of a novel coronavirus vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a novel coronavirus vaccine (product name unknown). On an unknown date, body temperature before vaccination: 36.4 degrees Celsius. On 10-Feb-2022, at 14:25, the patient received the 3rd vaccination with this vaccine. After the vaccination, there were no complaints from the patient. At the end of the observation of the patient's condition after vaccination, the vaccination staff watched the condition of the patient just in case, and it was found and reported to the physician that the patient had an ill complexion with a pulse oximeter reading of 90%. Since signs of cardiac failure were noted, the primary physician got contacted, and the patient was instructed to take a cab for a visit to the hospital. The patient was hospitalized. On 18-Feb-2022, the patient died. The outcome of suspected cardiac failure and ill complexion was unknown. Follow-up investigation will be made. Reporter comments continuation: There were no complaints from the patients in the post-vaccination observation. At the end of the 15-minute observation, the observer noticed that the patient's facial color was not good, so Sp02 was measured just in case, which showed 90%, and it was reported to the physician. The physician suspected worsening of cardiac failure and made a request to the hospital for medical examination after confirming	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							the patient's primary physician, and the patient was ordered to take a cab to the hospital. Based on this series of events, it is unlikely that this incident was caused by vaccination with this vaccine. Congestive cardiac failure was suspected as another factor. Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.	
[redacted]	SWITZERLAND	Chest pain, Death	84.00	Male	Cardiomyopathy(C); Myelodysplastic syndrome(C)	ASPIRIN CARDIO; CANDESARTANUM; BELOC ZOK; ZANIDIP; TORASEMIDE; CORDARONE; EUTHYROX; PANTOPRAZOLE; SINOPIL	This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (Death) and CHEST PAIN (Chest pain aggravated) in an 84-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005704) for COVID-19 vaccination. Co-suspect product included non-company product DARBEPOETIN ALFA (ARANESP) for an unknown indication. Concurrent medical conditions included Cardiomyopathy and Myelodysplastic syndrome. Concomitant products included ACETYLSALICYLIC ACID (ASPIRIN CARDIO), CANDESARTAN (CANDESARTANUM), METOPROLOL SUCCINATE (BELOC ZOK), LERCANIDIPINE HYDROCHLORIDE (ZANIDIP), TORASEMIDE, AMIODARONE HYDROCHLORIDE (CORDARONE), LEVOTHYROXINE SODIUM (EUTHYROX), PANTOPRAZOLE and LACIDIPINE (SINOPIL) for an unknown indication. On 06-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form and DARBEPOETIN ALFA (ARANESP) (unknown route) at an unspecified dose. On 07-Jan-2022, the patient experienced CHEST PAIN (Chest pain aggravated) (seriousness criteria death and hospitalization). The patient died on 14-Jan-2022. It is unknown if an autopsy was performed. The medical history included Heart surgery 2018. Report to a patient who died at the age of 84 on 14.01.22. In advance, the 1st Covid-19 mRNA vaccination with Spikevax (formerly COVID-19 Vaccine Moderna) took place on 06.01.22. According to information given by daughter data related to the result arose one day after vaccination, from 07.01.22, burning chest pain which intensified with light exertion or excitement. This pain was progressively worsening and led to emergency hospitalization via ambulance on 14.01.22. Arrived at the center hospital, the patient died a short time later. Due to a myelodysplastic syndrome, he was under therapy with the epoetin darbepoetin alfa, the last administration was at the same time as the vaccination on 06.01.22.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							Co-medication also included Nopil Forte and Sinopil with the ingredients Sulfamethoxazole of 800mg and Trimethoprim 160 mg. This patient experienced progressive burning chest pain one day after the first vaccination with Spikevax which was severely aggravated during physical exertion. The patient died 8 days after COVID-19 vaccination. As far as it can be determined, none autoptic determination of the cause of death was made in this case. There was none further information regarding possible clinical causes or diagnostic investigations of the exitus lethal. Company comment- This regulatory authority case concerns an 84-year-old male patient with relevant medical history of Cardiomyopathy and Myelodysplastic syndrome and concurrent use of darbepoetin alfa, who experienced serious unexpected events of chest pain and death. The chest pain occurred 1 day after the 1st dose of the mRNA-1273 whereas the patient passed away 7 days post-vaccination. Reportedly, the patient was hospitalized due to burning chest pain that intensified on light exertion or excitement. The patient progressively worsened and the patient was hospitalized. Following hospitalization, the patient passed away. The patient's advanced age and relevant medical history are possible confounders. The use of darbepoetin alfa is an additional confounder due to known increased risk for death in patients treated with this medication. The benefit-risk relationship of mRNA-1273 is not affected by this report.	
[redacted]	CZECH REPUBLIC	Asthenia, Back pain, Cardiac death, Dyspnoea, Fall, Pain, Syncope	73.00	Female	Dementia Alzheimer's type(C); Chronic obstructive pulmonary disease(C); Cachexia(C); Hypertension(C)	KALNORMIN; CONCOR; CALTRATE MINI CALS; AGEN; PRESTARIUM A; CONTROLOC	This case was received via European Medicines Agency (Reference number [redacted] on 23-Feb-2022 and was forwarded to Moderna on 23-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of FALL (Falls), PAIN (Generalized pain), BACK PAIN (Back pain), CARDIAC DEATH (Cardiac death), DYSPNOEA (Dyspnoe) and SYNCOPE (Syncope) in a 73-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Alzheimer's disease (incipient dementia), COPD, Cachexia and Hypertension. Concomitant products included POTASSIUM CHLORIDE (KALNORMIN), BISOPROLOL FUMARATE (CONCOR), CALCIUM CARBONATE, COLECALCIFEROL, COPPER SULFATE, MAGNESIUM OXIDE, MANGANESE SULFATE, ZINC OXIDE (CALTRATE MINI CALS), AMLODIPINE BESILATE (AGEN), PERINDOPRIL ARGININE (PRESTARIUM A) and PANTOPRAZOLE SODIUM SESQUIHYDRATE (CONTROLOC) for an unknown indication. On 27-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Subcutaneous) 1 dosage form. On 17-Jan-2022, the patient experienced FALL (Falls) (seriousness criterion medically significant), PAIN (Generalized pain) (seriousness criterion	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							medically significant), BACK PAIN (Back pain) (seriousness criterion medically significant), CARDIAC DEATH (Cardiac death) (seriousness criteria death and medically significant), DYSPNOEA (Dyspnoe) (seriousness criterion medically significant), SYNCOPE (Syncope) (seriousness criteria medically significant and life threatening) and ASTHENIA (Weakness). The patient died on 17-Jan-2022. The reported cause of death was Cardiac failure. An autopsy was not performed. At the time of death, FALL (Falls) and BACK PAIN (Back pain) outcome was unknown and PAIN (Generalized pain), DYSPNOEA (Dyspnoe), SYNCOPE (Syncope) and ASTHENIA (Weakness) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 17-Jan-2022, Chest X-ray: no signs of pneumothorax. pulmonary parenchyma is (normal) No signs of pneumothorax. pulmonary parenchyma is without focal changes. Heart contour is of normal size, mediastinum slim, without deviation. The diaphragm is segmented, the aorta is of normal shape. Conclusion - no signs of skeletal trauma or intrathoracic trauma.. For mRNA-1273 (Spikevax) (Subcutaneous), the reporter did not provide any causality assessments. No treatment information was reported. This is a fatal case concerning a 73-year-old female patient with medical conditions of Alzheimer's disease, COPD, Cachexia and Hypertension, who experienced the unexpected serious events of Fall, Pain, Back Pain, Cardiac Death, Dyspnea, and Syncope. The events were medically significant, life-threatening, and led to the eventual demise of the patient as reported by the regulatory authority. The events occurred in 21 days after receiving an unspecified dose of mRNA-1273 Vaccine. Chest X-ray results showed no signs of skeletal trauma or intrathoracic trauma, no other clinical or treatment details were given. The patient died on the onset date of events. The reported cause of death was Cardiac failure. An autopsy was not performed. The medical history of Alzheimer's disease, COPD, Cachexia and Hypertension remains a confounder. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.	
[redacted]	FRANCE	Drug ineffective, Vaccination failure	66.00	Male	Abdominal hernia(C); Non-Hodgkin's lymphoma(C); Psoriasis(C); Hypercholesterolaemia(C); Cyst(C); Carpal tunnel syndrome(C); Sinusitis(C); Aortic valve incompetence(C);	0	This case was initially received via European Medicines Agency (Reference numbe[redacted]) on 23-Feb-2022. The most recent information was received on 05-May-2022 and was forwarded to Moderna on 05-May-2022. This regulatory authority case was reported by a physician and describes the occurrence of VACCINATION FAILURE (Vaccination failure) and DRUG INEFFECTIVE (Drug ineffective) in a 66-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214022) for COVID-19 vaccination. Co-suspect products included non-company products CASIRIVIMAB, IMDEVIMAB (RONAPREVE) for COVID-19	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
					Tendon disorder(C)		prophylaxis, TOZINAMERAN (COMIRNATY) for COVID-19 vaccination, OBINUTUZUMAB (GAZYVARO) for Non-Hodgkin's lymphoma and LENALIDOMIDE (REVLIMID) for Non-Hodgkin's lymphoma. Concurrent medical conditions included Linea alba hernia in 1986, Non-Hodgkin's lymphoma in March 2017, Psoriasis, Hypercholesterolaemia, Cyst, Carpal tunnel syndrome, Maxillary sinusitis, Aortic incompetence in May 2021 and Tendinopathy. On 16-Feb-2021, the patient started OBINUTUZUMAB (GAZYVARO) (Oral) 1000 milligram. On 10-Mar-2021, the patient received first dose of TOZINAMERAN (COMIRNATY) (Intramuscular) 1 dosage form. On 07-Apr-2021, received second dose of TOZINAMERAN (COMIRNATY) (Intramuscular) dosage was changed to 1 dosage form. On 13-Sep-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 27-Sep-2021, the patient started LENALIDOMIDE (REVLIMID) (Oral) 20 milligram. On 25-Oct-2021, the patient started CASIRIVIMAB, IMDEVIMAB (RONAPREVE) (Intravenous) 600 milligram. On an unknown date, the patient experienced VACCINATION FAILURE (Vaccination failure) (seriousness criterion death). an unknown date, the patient experienced DRUG INEFFECTIVE (Drug ineffective) (seriousness criterion death). The reported cause of death was Drug ineffective and Vaccination failure. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 04-Jan-2022, SARS-CoV-2 test: positive (Positive) Positive. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. Treatment information was not provided. Dosage text given as R1. Company comment: This is a Vaccination failure Regulatory Authority case concerning a 66-year-old male patient, with relevant medical history of non-Hodgkin's lymphoma and aortic incompetence. Patient died 106 days after a dose of mRNA-1273 vaccine. The reported cause of death was Drug ineffective and Vaccination failure. It is unknown if an autopsy was performed. SARS-CoV-2 test with positive result was reported approximately 3 months and 20 days after mRNA-1273 vaccine. Medical history of non-Hodgkin's lymphoma and aortic incompetence could be confounders for the fatal outcome. Co-suspect products included	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							non-company products: Casirivimab, Imdevimab, Obinutuzumab and Lenalidomide. Primary vaccination completed with Pfizer vaccine, which remains as a co-suspect product. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 05-May-2022: Follow Up received with significant information as Co-suspect drug added.	
[redacted]	FRANCE	Cardio-respiratory arrest, Ischaemic stroke	46.00	Female	Dyslipidaemia(C); Asthma(C); Depression(C); Diabetes mellitus(C); Hypertension(C); Gastric banding; Endometriosis(C); Non-alcoholic fatty liver(C); Bundle branch block right(C); Obesity(H); Gastrooesophageal reflux disease(C); Sleep apnoea syndrome(H)	ATORVASTATINE EG; SERETIDE; TRIENTINE DICHLORHYDRATE; LOXENIL; CHLORHYDRATE DE PROCAINE; ESOMEPRAZOLE; OZEMPIC; METFORMINE PHR; COAPROVEL	This case was received via European Medicines Agency (Reference number: [redacted] on 23-Feb-2022 and was forwarded to Moderna on 23-Feb-2022. This regulatory authority case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of CARDIO-RESPIRATORY ARREST (Cardio-respiratory arrest) and ISCHAEMIC STROKE (Ischemic stroke) in a 46-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 008G21A) for COVID-19 vaccination. The patient's past medical history included Morbid obesity, Sleep apnea and Gastric banding. Concurrent medical conditions included Dyslipidaemia, Allergic asthma, Depression, Diabetes, Hypertension arterial, Endometriosis, Nonalcoholic fatty liver disease, Incomplete right bundle branch block and Gastrooesophageal reflux disease. Concomitant products included ATORVASTATIN CALCIUM (ATORVASTATINE EG), FLUTICASONE PROPIONATE, SALMETEROL XINAFOATE (SERETIDE), TRIENTINE DIHYDROCHLORIDE (TRIENTINE DICHLORHYDRATE), LINEZOLID (LOXENIL), PROCAINE HYDROCHLORIDE (CHLORHYDRATE DE PROCAINE), ESOMEPRAZOLE, SEMAGLUTIDE (OZEMPIC), METFORMIN HYDROCHLORIDE (METFORMINE PHR) and HYDROCHLOROTHIAZIDE, IRBESARTAN (COAPROVEL) for an unknown indication. On 17-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 04-Jan-2022, the patient experienced CARDIO-RESPIRATORY ARREST (Cardio-respiratory arrest) (seriousness criterion death) and ISCHAEMIC STROKE (Ischemic stroke) (seriousness criterion death). The patient died on 08-Jan-2022. The reported cause of death was stroke. An autopsy was not performed. On 17-Dec-2021, the patient received R1 dose of mRNA-1273 (Spikevax). Treatment information was not provided. Company comment:	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							This regulatory case concerns a 46-year-old, female patient with medical history of Morbid obesity, Sleep apnea, Dyslipidaemia, Diabetes, Hypertension arterial, Nonalcoholic fatty liver disease and Incomplete right bundle branch block, who experienced fatal unexpected event of cardio-respiratory arrest and fatal unexpected AESI event of ischaemic stroke, approximately 19 days after receiving a dose of mRNA-1273 Vaccine and the patient died 4 days after the onset of the events. Autopsy was not performed, and the cause of death was reported as Ischaemic stroke. Medical history of Morbid obesity, Dyslipidaemia, Diabetes, Hypertension arterial and Incomplete right bundle branch block could be contributory to the events cardio-respiratory arrest and ischaemic stroke. Nonalcoholic fatty liver disease and sleep apnea could be risk factors for the outcome. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events seriousness assessed as per Regulatory Authority reporting.	
[redacted]	JAPAN	Cardio-respiratory arrest, Decreased appetite, Loss of consciousness, Myocardial infarction, Pyrexia	97.00	Male	Myocardial infarction(H); Emphysema(C); Cardiac failure(C); Pulmonary tuberculosis(C); Hypertension(C); Dementia Alzheimer's type(C)	CLOPIDOGREL; MEMANTINE; METHYCOBAL; VITAMEDIN S	This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 22-Feb-2022. The most recent information was received on 11-Mar-2022 and was forwarded to Moderna on 18-Mar-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician was received via the PMDA (Ref, [redacted] On 11-Mar-2022, additional information was received from a physician. On an unknown date, the patient received the 1st dose of a COVID-19 vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a COVID-19 vaccine (product name unknown). On 18-Feb-2022, the patient received the 3rd vaccination with this vaccine. On 19-Feb-2022, in the daytime, pyrexia of 38s degrees Celsius developed. After returning home, the patient took acetaminophen orally. Subsequently, the fever subsided. On an unknown date, anorexia was noted. On 20-Feb-2022, pyrexia of 37s degrees Celsius was observed, and the patient took acetaminophen orally. The patient only drank water and had a light meal. On 21-Feb-2022, around 07:00, the patient defecated. At 07:15, the patient was encouraged to drink water. Around 08:00, it was found that the patient was unconscious when being moved to a wheelchair. Therefore, an ambulance call was made. When the ambulance team arrived, cardiopulmonary resuscitation was performed with cardio-pulmonary arrest. The patient was transported to a hospital. Although cardiopulmonary resuscitation was conducted about an hour, the patient remained to be in a state of cardiopulmonary arrest. The patient was already dead at the time of arrival at the hospital. Around 09:10, the patient was confirmed dead. No autopsy was performed. There was a possibility of the recurrence of myocardial infarction. The outcome of pyrexia, anorexia, unconsciousness, and possibility of the recurrence of myocardial infarction was unknown. The outcome of cardio-pulmonary arrest was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: The association between the cause of death and the adverse events is unknown, but the possibility cannot be ruled out. Since the possibility cannot be ruled out, the occurrence of adverse events is temporally related to the timing of administration of this vaccine. The occurrence of adverse events	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							is not associated with concomitant drugs because the drugs were regular medication for the patient and were unlikely to be related. It cannot be ruled out that the occurrence of adverse events may have been related to the pathophysiological factors of myocardial infarction and cardiac failure After the vaccination, the patient experienced pyrexia, anorexia, and dehydration; therefore, the possibility of hypercoagulability cannot be ruled out and the possibility of the recurrence of myocardial infarction can be considered. However, blood tests were not performed, and thus the details are unknown. Follow-up received on 11-MAR-2022 Updated: Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments Company Comment: Although the event of myocardial infarction developed after the administration of ELASOMERAN, preexisting conditions are also considered to have affected the event. Although the event of cardio-respiratory arrest developed after the administration of ELASOMERAN, it is possible that a concurrent event may have affected the event.	
[redacted]	JAPAN	Arrhythmia, Cardio-respiratory arrest	80.00	Male	Angina pectoris(C); COMIRNATY; COMIRNATY	0	This case was initially received via Takeda Pharmaceuticals (Reference number:[redacted] on 24-Feb-2022. The most recent information was received on 14-Mar-2022 and was forwarded to Moderna on 22-Mar-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a pharmacist, was received via the PMDA (Ref, [redacted]. On 14-Mar-2022, follow-up information was received from a physician. On an unknown date, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 17-Feb-2022, the patient received the 3rd dose of this vaccine. On 18-Feb-2022, at 18:30, it was the last time when the patient was confirmed healthy. Around 19:00, lethal arrythmia developed. A family member found the patient taking a bath and called an ambulance. When the ambulance team made contact, the patient was in a state of cardio-respiratory arrest. The initial waveform was asystole. At 19:40, the patient entered the emergency outpatient department of the reporting hospital. At 19:48, adrenaline 1 mg/mL was injected intravenously. At 19:52, adrenaline 1 mg/mL was injected intravenously. At 19:57, adrenaline 1 mg/mL was injected intravenously. At 20:00, adrenaline 1 mg/mL was injected intravenously. At 20:03, adrenaline 1 mg/mL was injected intravenously. At 20:06, adrenaline 1 mg/mL was injected intravenously. At 20:10, adrenaline 1 mg/mL was injected intravenously. Though intravenous injections were carried out seven times in total, the spontaneous circulation was not returned. At 20:11, death was pronounced. At 20:24, the obvious cause of death could not be indicated in diagnostic imaging CT at the time of death. At 20:41, an autopsy was performed. According to the postmortem certificate, the cause of death was lethal arrhythmia, and the time from onset to death was short. No autopsy was performed. The outcome of lethal arrythmia and cardio-respiratory arrest (CPA) was reported as fatal. No follow-up investigation will be made. Follow-up received on 14-MAR-2022 Updated: Other Relevant	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							History, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.	
[redacted]	JAPAN	Cardiac arrest, Cardiac death, Myocardial infarction, Poriomania, Thrombosis, Wound	73.00	Male	Diabetes mellitus(C); Hypertension(C); Cerebral infarction(C); COMIRNATY; COMIRNATY	NIFEDIPINE; GLIMEPIRIDE; APRINDINE HYDROCHLORIDE; METFORMIN HYDROCHLORIDE; VOGLIBOSE	This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 24-Feb-2022. The most recent information was received on 17-Mar-2022 and was forwarded to Moderna on 24-Mar-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, [redacted]). On 17-Mar-2022, follow-up information was received from a physician. The patient made regular visits to another hospital for diabetes mellitus, hypertension, and late effects of cerebral infarction. On 27-Jun-2021, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 18-Jul-2021, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 15-Feb-2022, the patient made a regular visit to a hospital. There were no particular abnormalities. On 17-Feb-2022, the patient did not have dinner due to physical deconditioning. There were no symptoms such as pyrexia. On 18-Feb-2022, the patient had a light meal. On 20-Feb-2022, the patient received the 3rd vaccination with this vaccine. At night, the patient had poriomania. On 21-Feb-2022, in the morning, the family member confirmed traumatic injury on the head and right lower leg. The patient had no particular symptoms until around noon. After 18:00, the patient was sitting leaning against the bed and did not respond to calls. At 18:31, an ambulance was called. At 18:44, the ambulance team arrived and confirmed the patient's cardio-respiratory arrest. Cardiopulmonary resuscitation was started for asystole, and the patient was transported to the reporting hospital. Administration of adrenaline 2A was performed. At 19:03, the patient was race to the reporting hospital. The patient made an initial visit to the reporting hospital. The patient remained in the asystole state. A total of 8A of adrenaline was used every three minutes, and cardiopulmonary resuscitation was performed, but waveforms did not change. There was no return of spontaneous circulation. At 19:39, the patient was confirmed dead. Postmortem diagnostic imaging was performed by CT. There were no obvious causes in the head or thoracoabdominal region. Blood sampling failed to identify the cause of death, and as a result of autopsy by the police, it was determined that there was no extrinsic factor, and the cause of death was determined as intrinsic cardiac death. There was a possibility of thrombosis or myocardial infarction due to high D-dimer levels. The outcome of poriomania and traumatic injury on the head and right lower leg was unknown. The outcome of asystole, possibility of thrombosis, and possibility of myocardial infarction was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: The causality with this vaccine cannot be ruled out. The possibility of thrombosis or myocardial infarction from high D-dimer levels and other factors and the influence of diabetes mellitus from hyperglycaemia are considered. The relationship between cause of death and adverse events is unknown. Follow-	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							up received on 17-MAR-2022 Updated: Patient Information, Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments Company Comment: Although the event of thrombosis and myocardial infarction developed after the administration of ELASOMERAN, preexisting conditions are also considered to have affected the event.	
[redacted]	JAPAN	Cardio-respiratory arrest, Death, Pyrexia	89.00	Female	Dementia(C); Femur fracture(C); Central venous catheterisation(H); Pneumonia aspiration(C)	FULCALIQ; MINERAMIC	This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 24-Feb-2022. The most recent information was received on 14-Mar-2022 and was forwarded to Moderna on 22-Mar-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, [redacted]. On 14-Mar-2022, follow-up information was received from a physician. On 03-Aug-2021, the patient experienced fracture of shaft of right femur. Conservation treatment was performed instead of surgery because the patient was elderly and had dementia. On 19-Aug-2021, the patient experienced aspiration pneumonia concurrently and was diagnosed with inability to take anything by mouth. On 02-Sep-2021, central intravenous catheter was placed. On 21-Sep-2021, the patient hospitalized in the reporting hospital for the purpose of continued care. Right femur fracture was avulsed, and bone fusion was inadequate. The previous physician pointed out transverse colon tumor, but the details were unknown. The patient had been in a relatively stable condition although pyrexia developed occasionally. On an unknown date, the patient received the 1st dose of a COVID-19 vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a COVID-19 vaccine (product name unknown). On 01-Feb-2022, the patient experienced pyrexia, which was treated as aspiration pneumonia. Antibiotics were administered. On 06-Feb-2022, pyrexia resolved. On 09-Feb-2022, the patient underwent blood test before the vaccination with this vaccine, but there were no findings of infection. At 14:30, the patient received the 3rd vaccination with this vaccine. On 11-Feb-2022, in the early evening, the patient experienced a single episode of pyrexia of 37.4 degrees Celsius. On 12-Feb-2022, the patient had recurrent low-grade fever until the early evening. On 15-Feb-2022, thereafter, there was no pyrexia. Vital signs and level of consciousness were unchanged. On 23-Feb-2022, in the early evening, body temperature was 36.6 degrees Celsius, PR was 82, and SpO2 was 98%. On 24-Feb-2022, at 00:00, the patient was asleep. At 05:00, the patient was checked on and found in a state of respiratory arrest. The patient died. The cause of death was geromarasmus. No autopsy was performed. The outcome of pyrexia was resolved. The outcome of cardio-respiratory arrest was unknown. No follow-up investigation will be made. Reporter comments continuation: The occurrence of adverse events is not related to concomitant drugs. The possibility of sudden pathological changes is considered because of incomplete fusion after femur fracture, central venous nutrition management, dementia, and decreased cardiopulmonary function due to advanced age. The relationship to this vaccine is unknown. The relationship between the cause of death and adverse events is	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							unknown. Follow-up received on 14-MAR-2022 Updated: Patient Information, Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments The temporal relationship between the occurrence of adverse events and timing of administration of this vaccine is unknown. Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.	
[redacted]	FRANCE	Dyspnoea, General physical health deterioration, Idiopathic pulmonary fibrosis, Infection, Pneumonitis, Pyrexia	77.00	Male	Dyslipidaemia(H); Hypertension(H); Prostate cancer(H); Rheumatoid arthritis(H); Atrial fibrillation(H); Pulmonary fibrosis(H); Lung lobectomy; Myocardial infarction(H); Lung neoplasm malignant(H)	ELIQUIS; AMIODARONE; CORTANCYL; SPECIAFOLDINE; EUPANTOL; TIMETH; BISOPROLOL EG	This case was initially received via European Medicines Agency (Reference number: [redacted] on 24-Feb-2022. The most recent information was received on 21-Mar-2022 and was forwarded to Moderna on 21-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of GENERAL PHYSICAL HEALTH DETERIORATION (General physical health deterioration), PNEUMONITIS (Lung inflammation), PYREXIA (Pyrexia), INFECTION (Infection), IDIOPATHIC PULMONARY FIBROSIS (Exacerbation of idiopathic pulmonary fibrosis) and DYSPNOEA (Breath shortness) in a 77-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Dyslipidaemia, Hypertension arterial, Prostate cancer, Arthritis rheumatoid, AFib, Fibrosis lung, Infarct myocardial, Cancer of lung and Lung lobectomy. Concomitant products included APIXABAN (ELIQUIS), AMIODARONE, PREDNISONE (CORTANCYL), FOLIC ACID (SPECIAFOLDINE), PANTOPRAZOLE SODIUM SESQUIHYDRATE (EUPANTOL), TIEMONIUM METHYLSULPHATE (TIMETH) and BISOPROLOL FUMARATE (BISOPROLOL EG) for an unknown indication. On 08-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 22-Dec-2021, the patient experienced GENERAL PHYSICAL HEALTH DETERIORATION (General physical health deterioration) (seriousness criterion death), PNEUMONITIS (Lung inflammation) (seriousness criterion death), PYREXIA (Pyrexia) (seriousness criterion death), INFECTION (Infection) (seriousness criterion death), IDIOPATHIC PULMONARY FIBROSIS (Exacerbation of idiopathic pulmonary fibrosis) (seriousness criterion death) and DYSPNOEA (Breath shortness) (seriousness criterion death). The patient died on 27-Jan-2022. The reported cause of death was exacerbation of pulmonary fibrosis. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 19-Jan-2022, SARS-CoV-2 test: negative (Negative) Negative.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on 08-Dec-2021. Date of last administration of Spikevax was 8-DEC-2021. No treatment medication was provided. Company comment. This fatal regulatory authority case concerns a 77 year old, male patient with relevant medical history of dyslipidemia, hypertension, myocardial infarction, prostate cancer, rheumatoid arthritis, atrial fibrillation, lung fibrosis and lung cancer, who experienced unexpected, serious fatal events of general physical health deterioration, pneumonitis, pyrexia, infection, idiopathic pulmonary fibrosis and dyspnoea, 14 days after receiving a dose of mRNA-1273. SARS-Cov-2 test was performed with negative results. Clinical course and treatment details were not reported. The cause of death was reported as exacerbation of pulmonary fibrosis. The patient died on 27-Jan-2022, approximately 7 weeks after vaccination. It is unknown if an autopsy was performed. The age and medical history of the patient remain as confounders for the events and fatal outcome. The benefit risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 21-Mar-2022: Significant Follow-up received : Patient's date of death , cause of death, medical history, new event and concomitant product updated	
[redacted]	NETHERLANDS	Asthenia, Chills, Cough, Insomnia, Malaise, Myalgia, Nasopharyngitis, Nausea, Peripheral coldness, Vomiting	72.00	Male	Pneumonia(H); Tobacco user(C); Aortic aneurysm(H); Chronic obstructive pulmonary disease(C); Renal cancer(H); COMIRNATY; COMIRNATY	0	This case was initially received via European Medicines Agency (Reference number: [redacted] on 25-Feb-2022. The most recent information was received on 24-Mar-2022 and was forwarded to Moderna on 24-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of ASTHENIA (Loss of strength, arm (s) first, then body), COUGH (Cough (flu symptoms?)), NASOPHARYNGITIS (Have a cold(flu symptoms?)) and PERIPHERAL COLDNESS (ice-cold hands) in a 72-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Pneumonia (He also had pneumonia exactly 3 years ago. That's when that prednisone cure helped him on top of it. After that previous pneumonia, his lungs were completely checked and I was anxious that a spot would be found on his lungs, but they were clean!! He's recovered from that pneumonia and no longer bothered it.) in January 2019, Abdominal aneurysm in 2019 and Renal cancer (He had pneumonia 3 years ago and completely recovered from prednisone treatment. Then his lungs were checked and were clean but there was a spot (cancer) on his kidney. The tumour was in his kidney and was removed about 2.5 years ago, received 'free	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							letter' after examination pathologist and again came out of the top fit, did not need a chemo cure (rinsing in the beginning).) in 2019. Previously administered products included for Product used for unknown indication: BioNTech/Pfizer vaccine (Comirnaty) COVID-19 VACCINE PFIZER SUSPENSION FOR INJECTION 0.3 ML on 31-May-2021 and BioNTech/Pfizer vaccine (Comirnaty) COVID-19 VACCINE PFIZER SUSPENSION FOR INJECTION 0.3 ML on 15-Jul-2021. Past adverse reactions to the above products included Injection site pain with BioNTech/Pfizer vaccine (Comirnaty) COVID-19 VACCINE PFIZER SUSPENSION FOR INJECTION 0.3 ML and BioNTech/Pfizer vaccine (Comirnaty) COVID-19 VACCINE PFIZER SUSPENSION FOR INJECTION 0.3 ML. Concurrent medical conditions included Smoker (I don't have any numbers. My dad smoked. Even when he was here, he went outside regularly.) and COPD. On 03-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 09-Jan-2022, the patient experienced ASTHENIA (Loss of strength, arm (s) first, then body) (seriousness criteria death and life threatening). On 10-Jan-2022, the patient experienced VOMITING (vomiting, productive in the beginning, later more prone to vomit, walked around with a bucket, but bucket remained empty.), MYALGIA (Muscle Pain), NAUSEA (nausea) and MALAISE (Don't feel good). On 17-Jan-2022, the patient experienced CHILLS (Cold shivers) and PERIPHERAL COLDNESS (ice-cold hands) (seriousness criteria death and life threatening). On 20-Jan-2022, the patient experienced COUGH (Cough (flu symptoms?)) (seriousness criteria death and life threatening) and NASOPHARYNGITIS (Have a cold(flu symptoms?)) (seriousness criteria death and life threatening). On 22-Jan-2022, the patient experienced INSOMNIA (Haven't slept in 72 hours. I still thought that was strange, I said to my father "if you feel sick or bad, then you would prefer to sleep, wouldn't you?", but he couldn't do that. Or very restless.). The patient died on 25-Jan-2022. The reported cause of death was copd. It is unknown if an autopsy was performed. At the time of death, INSOMNIA (Haven't slept in 72 hours. I still thought that was strange, I said to my father "if you feel sick or bad, then you would prefer to sleep, wouldn't you?", but he couldn't do that. Or very restless.) had not resolved and VOMITING (vomiting, productive in the beginning, later more prone to vomit, walked around with a bucket, but bucket remained empty.), CHILLS (Cold shivers), MYALGIA (Muscle Pain), NAUSEA (nausea) and MALAISE (Don't feel good) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In December 2019, Physical examination: not alarming Measurement aneurysm: the measurement was not alarming, actually not to worry about but came back after half a year to see if there was any growth.	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							In June 2020, Physical examination: no need for concern Aneurysm measurement: The second measurement was about half a year later. When it turned out that no growth had been detected, there was no need for concern, a half-yearly measurement was not necessary.. On 17-Jan-2021, SARS-CoV-2 test: negative (Negative) negatively. Concomitant medications were not reported . Treatment information was not provided. Company Comment: This is a regulatory, fatal case concerning a 72-year-old male patient with reported medical history of COPD, Smoker, Abdominal aneurysm, Renal cancer, and previous COVID-19 Vaccination history with BioNTech/Pfizer vaccine (Comirnaty), who experienced the unexpected serious events of Nasopharyngitis, Cough, Peripheral Coldness and Asthenia. The events were life-threatening and led to the eventual demise of the patient as reported by the regulatory authority. The event Asthenia 6 days after receiving a dose (3rd dose of the COVID-19 Vaccination) of mRNA-1273 Vaccine. Peripheral Coldness occurred 14 days later while Cough and Nasopharyngitis occurred 17 days later. The patient died approximately 22 days after a dose of mRNA-1273 vaccine was received. It is unknown if autopsy was performed. The reported cause of death was COPD. The medical history of COPD, Smoker, Abdominal aneurysm, and Renal cancer remains a confounder. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 24-Mar-2022: Significant follow up appended: Relevant medical history details updated, Event and lab test added. On 24-Mar-2022: Translation received on 29-MAR-2022 contains translated event verbatim with no new information.	
[redacted]	AUSTRIA	Cardiac failure acute	64.00	Female	Hyperlipidaemia(H); Tobacco abuse(H); Ventricular hypertrophy(H); SARS-CoV-2 test negative(H); Arteriosclerosis(H); Ischaemic nephropathy(H); Left ventricular dilatation(H); Hypertension(C)	LASIX [FUROSEMIDE]; AMILOSTAD; ATORVASTATIN; EUTHYROX; DEDOLOR	This case was received via European Medicines Agency (Reference number: [redacted] on 28-Feb-2022 and was forwarded to Moderna on 28-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CARDIAC FAILURE ACUTE (acute cardinal decompensation) in a 64-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Hyperlipidaemia, Nicotine abuse, Ventricular hypertrophy, COVID-19 PCR test negative on 12-Jun-2021, Atherosclerosis generalised, Ischaemic nephropathy and Left ventricular dilatation. Concurrent medical conditions included Hypertension arterial. Concomitant products included FUROSEMIDE (LASIX [FUROSEMIDE]), AMLODIPINE BESILATE (AMILOSTAD), ATORVASTATIN, LEVOTHYROXINE SODIUM	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							(EUTHYROX) and DICLOFENAC SODIUM (DEDOLOR) for an unknown indication. On 09-Jun-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 12-Jun-2021, the patient experienced CARDIAC FAILURE ACUTE (acute cardinal decompensation) (seriousness criterion death). The patient died on 12-Jun-2021. The reported cause of death was Acute decompensated heart failure. An autopsy was performed. The autopsy-determined cause of death was Acute decompensated heart failure. Dosage text for suspect spikevax reported as first partial vaccination/first dose. On 12-Jun-2021 at 12:16, The patient died. No treatment information was provided Company comment: This is a fatal regulatory case concerning a 64-year-old female patient with medical history of hypertension arterial, nicotine abuse, atherosclerosis generalized, ischemic nephropathy, ventricular hypertrophy and left ventricular dilation, who experienced the fatal event cardiac failure acute (AESI), approximately 3 days after the first dose of mRNA-1273. Patient died on the same day the event occurred. The reported cause of death was Acute decompensated heart failure. An autopsy was performed. The autopsy-determined cause of death was Acute decompensated heart failure. Above mentioned patient's medical history remains as confounder for the event. The benefit-risk relationship of mRNA-1273 is not affected by this report.	
[redacted]	NETHERLANDS	Cerebrovascular accident, Respiratory acidosis	82.00	Male	Hypertension(C); Resuscitation(H); Aortic aneurysm(H); Atrial fibrillation(C); Coronary artery bypass; Cardiac assistance device user(C); Percutaneous coronary intervention; Wheelchair user(C); Ex-tobacco user(H); Drug	METOPROLOL-BC; SALBUTAMOL A; TIOTROPIUM; ACETYLSALICYLZUUR	This case was received via European Medicines Agency (Reference numbe[redacted] on 23-Feb-2022 and was forwarded to Moderna on 23-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of RESPIRATORY ACIDOSIS (respiratory acidosis) and CEREBROVASCULAR ACCIDENT (Patient has become suddenly reduced admissible 1 day after booster vaccination, presumably due to cerebral cause such as cerebral hemorrhage/infarction) in an 82-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 216036) for COVID-19 vaccination. The patient's past medical history included Resuscitation (2011 abdominal aortic aneurysm wv tubular prosthesis, hereby resuscitation) in 2011, Abdominal aortic aneurysm in 2011, Ex-smoker in 1973, Coronary artery bypass graft in 2019, Percutaneous coronary intervention (2007 PTCA ramus	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
					hypersensitivity; Aortic aneurysm repair; Plasmacytoma(C); COMIRNATY; COMIRNATY; COMIRNATY; COMIRNATY		descendens anterior) in 2007 and Aortic aneurysm repair (bioprosthesis) in 2011. Previously administered products included for Product used for unknown indication: COMIRNATY on 24-Mar-2021, BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST on 01-Jun-2021, BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST on 01-Jun-2021, BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST on 01-Jun-2021. Past adverse reactions to the above products included Balance difficulty with BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST; Dizziness with BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST; Dyspnoea with BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST; and No adverse reaction with COMIRNATY. Concurrent medical conditions included Hypertension, Atrial fibrillation (arrhythmias-atrial fibrillation. due to high risk of bleeding, no oral anticoagulation started, only acetylsalicylic acid), Implantable defibrillator user (not mentioned by reporter, but described in autopsy journal), Wheelchair user, Penicillin allergy and Plasmacytoma (From history as noted in autopsy report: Isolated plasmacytoma Th5/Th6. No Kahler at follow-up). Concomitant products included METOPROLOL TARTRATE (METOPROLOL-BC), SALBUTAMOL (SALBUTAMOL A), TIOTROPIUM and ACETYLSALICYLZUUR for an unknown indication. On 30-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 31-Dec-2021, the patient experienced RESPIRATORY ACIDOSIS (respiratory acidosis) (seriousness criterion death) and CEREBROVASCULAR ACCIDENT (Patient has become suddenly reduced admissible I day after booster vaccination, presumably due to cerebral cause such as cerebral hemorrhage/infarction) (seriousness criterion death). The patient died on 02-Jan-2022. The reported cause of death was respiratory acidosis suspected in cerebral hypoventilation (skull obduction follows) and hypoventilation by cerebral cause. An autopsy was performed. The autopsy-determined cause of death was no abnormalities seen to organs. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 03-Jan-2021, Autopsy: no particularities ABDOMEN: The liver weighs 1086 g. No particularities at cut. The spleen weighs 182 g. No specifics at cut. Due to the presence of a trouser prosthesis in the abdominal aorta. Both kidneys weigh 300 g. No specifics at cut. Gastrointestinal tract and pancreas: no	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							particularities. Bladder and prostate: no particularities., no abnormalities externally BRAIN: A skull production was performed. The brain weigh 1680 g. No abnormalities externally. These will be investigated in university center, hypereosinophilia and contraction band necrosis MICROSCOPY: Bone marrow: reactive changes. Adrenal glands: no specifics. Liver and spleen: low centrilobular congestion of the liver. Slight expansion of the red pulp. No splenitis. Pancreas: Advanced Autolysis. Left kidney: no specifics. Right kidney: no specifics. Left lung: no details. Right lung no specifics. Myocardial: picture of chronic ischemic cardiomyopathy. Under the form of multiple spotted old fibrous fireplaces. Microscopically no features of recent ischemia. Local some hypereosinophilia and contraction band necrosis. However, no infiltration of inflammation cells. There was extensive sampled. and no particularities. The left lung weighs 333 g, the right lung 372 g. No specifics at cut. No embolisms. The heart shows extensive adhesions to previous coronary surgery where it is technically impossible to properly assess the internal status of the coronaries. Presence of a pacemaker. The aortic thoracic aorta exhibits moderately pronounced atherosclerosis. However, the carotid arteries are easily accessible. The left ventricular wall has a thickness of 3 cm with image matching a concentric left ventricular hypertrophy. In the LDH test, there is a fairly pronounced decolouration of the left ventricular wall. Recent ischemia? Infrared? Agonal? Throat skeleton, trachea, esophagus and thyroid: no particularities.. In January 2021, Autopsy: obduction has occurred Obduction has occurred, in which the organs were not diagnosed with any pathology that could explain death.. In December 2021, SARS-CoV-2 test: negative (Negative) negative. On 31-Dec-2021, Laboratory test: no notable abnormalities (Inconclusive) platelet 130x10^9 (platelets have been slightly lowered since 2019), CRP 14, pH 7.24, pCO2 94, bicarbonate 30.5, Po2 111, coagulation values have not been determined. No notable abnormalities. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No treatment information were given. Company comment: This is a regulatory authority case concerning a 82-year-old, male patient with relevant medical history of hypertension, abdominal aortic aneurysm in 2011, resuscitation (2011, abdominal aortic aneurysm with tubular prosthesis, hereby resuscitation), aortic aneurysm repair (2011, bioprosthesis) atrial fibrillation (due to high risk of bleeding, no oral anticoagulation started, only acetylsalicylic acid), coronary artery bypass graft in 2019, implantable defibrillator user, percutaneous coronary intervention (2007 PTCA ramus descendens anterior), wheelchair user, former smoker in 1973 and Plasmacytoma and with vaccine history of receiving 2 doses of another brand of Covid-19 vaccine (Covid-	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							19 vaccine Comirnaty) as previous doses, who experienced the unexpected serious (fatal according to regulatory authority) AESI event of presumably cerebrovascular accident and unexpected serious (fatal according to regulatory authority) event of respiratory acidosis. The events occurred approximately 1 day after the unknown dose number of mRNA-1273 vaccine administration. The reported cause of death was respiratory acidosis suspected in cerebral hypoventilation (skull obduction follows) and hypoventilation by cerebral cause. An autopsy was performed with autopsy findings of, obduction has occurred, in which the organs were not diagnosed with any pathology that could explain death. The autopsy-determined cause of death was no abnormalities seen to organs. The reported medical history remains confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	
[redacted]	FRANCE	Death	50.00	Male	Hypokalaemia(H); Alcoholism(H); Hypertension(H); Renal failure(H); Obesity(H); Polyneuropathy alcoholic(H)	0	This case was received via European Medicines Agency (Reference number: [redacted] on 28-Feb-2022 and was forwarded to Moderna on 28-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of DEATH (Death NOS) in a 50-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Hypokalaemia, Chronic alcoholism, Hypertension arterial, Insufficiency renal, Obesity and Alcoholic polyneuropathy. On 13-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. Death occurred on 08-Jan-2022 The patient died on 08-Jan-2022. The cause of death was not reported. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. Treatment information was not provided. Company Comment: This regulatory case concerns a 50-year-old, male patient with medical history of Hypertension, Renal Insufficiency, Chronic alcoholism, Alcoholic polyneuropathy, Obesity and Hypokalaemia, who experienced the unexpected, serious event of death. The event occurred 26 days after administration of a dose of the Moderna mRNA-1273 vaccine. No further details were provided and the cause of death was unknown. It is unknown if an autopsy was performed. The medical history of Hypertension, Renal Insufficiency, Chronic alcoholism, Alcoholic polyneuropathy, Obesity and Hypokalaemia remain as confounders. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
[redacted]	GERMANY	Death	59.00	Male	Chronic obstructive pulmonary disease(H)	0	This case was received via European Medicines Agency (Reference number: [redacted] on 01-Mar-2022 and was forwarded to Moderna on 01-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (diarrhoea) in a 59-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000110A) for COVID-19 vaccination. The patient's past medical history included COPD. On 18-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. Death occurred on 23-Dec-2021 The cause of death was not reported. It is unknown if an autopsy was performed. Patient's date of birth reported as 26-Aug-1962. Medical history was also included Diabetes. Relevant concomitant medications were not reported. Treatment information was not provided. Company Comment: This regulatory case concerns a 59-year-old, male patient with medical history of Chronic Obstructive Pulmonary Disease (COPD) and Diabetes, who experienced the unexpected, serious event of death. The event occurred 5 days after administration of the third dose of the Moderna mRNA-1273 vaccine. No further details were provided and the cause of death was unknown. It is unknown if an autopsy was performed. The medical history of COPD and Diabetes remain as confounders. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report.	[redacted]
[redacted]	LATVIA	Hypertrophic cardiomyopathy, Sudden death	45.00	Male	Haemorrhoids(H); Spinal osteoarthritis(C); Essential hypertension(C); Anal ulcer(H); Goitre(C); Splenomegaly(C); Arteriosclerosis(C); Pancreatitis chronic(C); Hypothyroidism(C); Dyslipidaemia(C); Spinal osteoarthritis(C); Autoimmune thyroiditis(C); Myocardial fibrosis(C)	TRIVERAM; LEVOTHYROXINE	This case was initially received via European Medicines Agency (Reference number: [redacted] on 02-Mar-2022. The most recent information was received on 10-May-2022 and was forwarded to Moderna on 10-May-2022. This regulatory authority case was reported by a physician and describes the occurrence of SUDDEN DEATH (Sudden death) and HYPERTROPHIC CARDIOMYOPATHY (Hypertrophic cardiomyopathy) in a 45-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005843) for COVID-19 vaccination. The patient's past medical history included Haemorrhoids (stage 2) on 24-Oct-2019 and Anal ulcer on 24-Oct-2019. Concurrent medical conditions included Lumbar spondylosis since 2007, Essential hypertension since 2018, Struma (Diffuse struma), Splenomegaly, Atherosclerosis generalised (atherosclerosis mostly in aorta and coronary artery), Chronic pancreatitis (chronic indurative pancreatitis), Hypothyroidism (subcompensated hypothyroidism) since November 2018, Dyslipidaemia, Spondyloarthrosis since 2007, Autoimmune	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							thyroiditis (Chronic autoimmune thyroiditis, Hashimoto type) since November 2018 and Cardiosclerosis (atherosclerotic cardiosclerosis). Concomitant products included AMLODIPINE BESILATE, ATORVASTATIN CALCIUM, PERINDOPRIL ARGININE (TRIVERAM) for Arterial hypertension, LEVOTHYROXINE from 01-Feb-2019 to an unknown date for Autoimmune thyroiditis and Hypothyroidism. On 14-Jan-2022, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 30-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced SUDDEN DEATH (Sudden death) (seriousness criterion death) and HYPERTROPHIC CARDIOMYOPATHY (Hypertrophic cardiomyopathy) (seriousness criteria death and medically significant). The patient died on 30-Jan-2022. The reported cause of death was Pulmonary oedema, Cerebral oedema and Hypertrophic cardiomyopathy. An autopsy was performed, but no results were provided. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 30-Jan-2022, Blood ethanol: 1-19 1.19%%. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered HYPERTROPHIC CARDIOMYOPATHY (Hypertrophic cardiomyopathy) to be unlikely related. No further causality assessment was provided for SUDDEN DEATH (Sudden death). No treatment drug details was reported. It was reported as the Causal association of Hypertrophic cardiomyopathy and its complications pulmonary and cerebral oedema with the 2nd dose of Spikevax is assessed unlikely by the SAM as underlying disease Essential Hypertension provides plausible explanation of clinical symptoms. Company Comment: This regulatory authority case concerns a 45 year old male patient with relevant medical history of hypertension , Atherosclerosis Generalized , Dyslipidemia , autoimmune thyroiditis , Cardiosclerosis and hypothyroidism , who experienced Serious (fatal) unexpected events of Sudden death and Hypertrophic Cardiomyopathy which occurred 16 days post vaccination with the 2nd dose of mRNA-1273 vaccine. The information regarding the dose 1 Covid 19 vaccine of this patient was not reported. The details surrounding the death of this patient , treatment information if any was given were not included in this report. Ethanol level was done reported at 1.19 % . The reported cause of dearth was pulmonary edema , cerebral edema and hypertrophic cardiomyopathy . An autopsy was done however results were not provided. The above mentioned medical history of this patient are all considered as confounders for the events.	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							The benefit -risk relationship of mRNA -1273 (Moderna Covid 19 Vaccine) is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 10-May-2022: Significant Follow up appended: Patient medical history, Autopsy, death date, Lab data, suspect drug dosage details and additional event was added. previous medical history: Obstructive nephropathy, Gallstones, Kidney stone, Primary hypertension and Myofascial pain syndrome was deleted	
[redacted]	JAPAN	Death	80.00	Female	Hypertension(C); Atrial fibrillation(C); Osteoporosis(C); Cardiac failure(C); Spinal compression fracture(H); Hypercholesterolaemia(C); Muscle spasms(H); Oedema peripheral(H); KETAS(H)	BONALON; FUROSEMIDE; AMLODIPINE; PITAVASTATIN CA; SHAKUYAKUKANZOTO; ELIQUIS; TAKAVENSU; AZILVA	This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 28-Feb-2022. The most recent information was received on 23-Mar-2022 and was forwarded to Moderna on 29-Mar-2022. This case was reported by a physician via a medical representative. On 23-Mar-2022, follow-up information was received from a physician. On an unknown date, the patient received the 1st dose of a COVID-19 vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a COVID-19 vaccine (product name unknown). On 25-Dec-2021, the patient visited a hospital as a routine. There were no abnormalities in particular. On 24-Feb-2022, the patient received the 3rd vaccination with this vaccine. There were no particular problems. On 25-Feb-2022, around 21:00, the patient died in the bathroom. This case was informed by the police. The cause and details were unknown. No follow-up investigation will be made. Reporter comments continuation: The occurrence of adverse events is not associated with concomitant drugs. The occurrence of the adverse event is related to the pathophysiological factors of atrial fibrillation because it may cause myocardial infarction and cerebral infarction. The event is not considered to have been caused by this vaccine. Follow-up received on 23-MAR-2022 Updated: Patient Information, Other Relevant History, Product Information, Event Information, Narrative, Reporter comments Company Comment: The event developed after the administration of ELASOMERAN and there is temporal relationship.	[redacted]
[redacted]	CZECH REPUBLIC	Decreased appetite, Diarrhoea, Ileus, Intestinal haemorrhage, Intestinal infarction, Mesenteric arterial occlusion, Nausea	77.00	Male	Myocardial ischaemia(C); Peripheral artery bypass; Vascular pseudoaneurysm(H); Arterial stenosis(C); Vascular graft occlusion(H); Prosthetic vessel implantation; Hypertension(C); Abstains from alcohol(H); Tobacco user(H); Hypertension(H); Peripheral artery bypass(H)	PRESTARIUM NEO COMBI; EBRANTIL KAKEN; ISOPTINO; STACYL	This case was initially received via European Medicines Agency (Reference number: [redacted] on 01-Mar-2022. The most recent information was received on 26-May-2022 and was forwarded to Moderna on 26-May-2022. This regulatory authority case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of INTESTINAL INFARCTION (bowel infarction), MESENTERIC ARTERIAL OCCLUSION (Occlusion mesenteric artery), INTESTINAL HAEMORRHAGE (Enterorrhagia) and ILEUS (ileus) in a 77-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included False aneurysm (in the groin, resection), Femoropopliteal artery bypass occlusion, Teetotaller since an unknown date, Smoker (20 cigarettes a day) since an unknown date, Arterial hypertension since an unknown	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							date, Femoropopliteal artery bypass since 2000, Femoral-popliteal shunt since 2000 and Prosthetic vessel implantation since an unknown date. Concurrent medical conditions included Ischemic heart disease, Arterial stenosis (60-70%, the left internal carotid artery) and Hypertension. Concomitant products included INDAPAMIDE, PERINDOPRIL ARGININE (PRESTARIUM NEO COMBI), URAPIDIL (EBRANTIL KAKEN), VERAPAMIL HYDROCHLORIDE (ISOPTINO) and ACETYLSALICYLIC ACID (STACYL) for an unknown indication. On 07-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. In January 2022, the patient experienced MESENTERIC ARTERIAL OCCLUSION (Occlusion mesenteric artery) (seriousness criteria death, hospitalization, medically significant and life threatening) and ILEUS (ileus) (seriousness criteria hospitalization, medically significant and life threatening). On 18-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced INTESTINAL INFARCTION (bowel infarction) (seriousness criteria death, hospitalization, medically significant and life threatening). On 20-Jan-2022, the patient experienced INTESTINAL HAEMORRHAGE (Enterorrhagia) (seriousness criteria hospitalization and medically significant), DIARRHOEA (diarrhea), DECREASED APPETITE (Appetite lost) and NAUSEA (Nausea). The patient died on 23-Jan-2022. The reported cause of death was Bowel infarction. An autopsy was not performed. At the time of death, INTESTINAL HAEMORRHAGE (Enterorrhagia), DIARRHOEA (diarrhea), DECREASED APPETITE (Appetite lost), NAUSEA (Nausea) and ILEUS (ileus) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 14-Jan-2022, Blood pressure measurement: 144/88 144/88 mmHg. On 14-Jan-2022, Body mass index: 25.82 25.82. On 14-Jan-2022, Ejection fraction: 65 65 percent. On 14-Jan-2022, Physical examination: abdomen soft, palpable, palpably painless, hepar n abdomen soft, palpable, palpably painless, hepar not enlarged, lien does not bump, tapottement bilaterally negative, Israeli negative, pathological resistance not palpable, per rectum painless, no resistance, stool normal consistency, no blood. On 20-Jan-2022, Activated partial thromboplastin time: 29.4 29.4 Siemens. On 20-Jan-2022, Activated partial thromboplastin time ratio: 1 1 Siemens. On 20-Jan-2022, Blood pressure measurement: 129/83 129/83 mmHg. On 20-Jan-2022, Body height: 175 175 centimetre. On 20-Jan-2022, Body mass index: 28,41 28,41. On 20-Jan-2022, C-reactive protein: 326 326 mg/L.	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							On 20-Jan-2022, Electrocardiogram: tachycardia, atrial fibrillation, horizontal axis, (abnormal) tachycardia, atrial fibrillation, horizontal axis, QRS 106 ms, T-wave positive, ST isoelectric. On 20-Jan-2022, Heart rate: 121 121/min. On 20-Jan-2022, Mean platelet volume: 11 11 fL. On 20-Jan-2022, Platelet count: 212 212 billion per litre. On 20-Jan-2022, Platelet distribution width: 13.5 13.5 fL. On 20-Jan-2022, Prothrombin time: 15.7 15.7 Siemens and 1.31 1.31 Siemens. On 20-Jan-2022, Red blood cell count: 5.18 5.18 trillion per litre. On 20-Jan-2022, Weight: 87 87 kilogram. On 20-Jan-2022, White blood cell count: 16.7 16.7 billion per litre. On 21-Jan-2022, Angiogram: occlusion of the superior mesenteric artery trunk, occlusion of the superior mesenteric artery trunk, defective saturation of most of the tenue (except the proximal jejunum and duodenum) and right colon. Tenue is slightly opacified from the collateral circulation only in the portovenous phase. Illusions, discreet effusion in the pelvis. Diverticles of sigma and descendens, cysts of the left kidney.. On 21-Jan-2022, C-reactive protein: 344 344 mg/L. On 21-Jan-2022, Chest X-ray: atherosclerosis of the aorta, otherwise a normal f (abnormal) atherosclerosis of the aorta, otherwise a normal finding on the intrathoracic organs. On 21-Jan-2022, Platelet count: 152 152 billion per litre. On 21-Jan-2022, White blood cell count: 8.6 8.6 billion per litre. Treatment information was not provided. Company comment: This regulatory authority case concerns a 77-year-old, male patient with relevant medical history of Femoropopliteal Artery Occlusion status post Femoropopliteal Artery Bypass Occlusion, Hypertension, Arterial Stenosis, Ischemic Heart Disease; Overweight (BMI: 25.82) and Smoking (20 cigarettes/day for unknown number of years), who experienced the unexpected, serious (fatal, life-threatening, hospitalization and medically significant) AESI of intestinal infarction; the unexpected, serious (fatal, life-threatening, hospitalization and medically significant) event of mesenteric arterial occlusion; the unexpected, serious (life-threatening, hospitalization and medically significant) event of ileus; the unexpected, serious (hospitalization and medically significant) event of intestinal haemorrhage; and other associated unexpected and expected, non-serious events. The events intestinal infarction, intestinal haemorrhage, and the non-serious events occurred approximately 1 month after receiving the third dose of the mRNA-1273 vaccine. The events mesenteric arterial occlusion and ileus occurred on unspecified dates in Jan2022 after receiving the third dose of the mRNA-1273 vaccine. Approximately 1 month (38 days) after vaccination (4 to 6 days before the onset of the events), physical examination findings and laboratory tests	

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							done were unremarkable except for the elevated blood pressure (BP) of 144/88 mmHg and Body mass index (BMI) of 25.82. After 6 days, the patient's heart rate was increased (121 beats/minute) but the BP was lower (129/83 mmHg). The BMI was noted to be higher (28.41) and the patient's weight had also increased (from 80 kg to 87 kg, unspecified time interval). The Electrocardiogram (ECG) showed 'tachycardia, atrial fibrillation, horizontal axis, QRS 106 ms, T-wave positive, ST isoelectric'. Blood tests showed elevated C-reactive protein (CRP) of 326 mg/L and Leukocyte count of 16.7 x 10^9/L. The following day, the Leukocyte count was normal (8.6 x 10^9/L) but the CRP was still elevated (344 mg/L). The Computerized Tomography Angiogram of the Abdomen and Pelvis (two-phase post-contrast) showed 'occlusion of the superior mesenteric artery trunk, defective saturation of most of the tenue (except the proximal jejunum and duodenum) and right colon. Tenue is slightly opacified from the collateral circulation only in the portovenous phase. Illusions, discreet effusion in the pelvis. Diverticles of sigma and descendens, cysts of the left kidney'. The Chest X-ray was unremarkable except for 'atherosclerosis of the aorta'. No further clinical information (including details about hospitalization) was available for medical review. Treatment information was also not provided. The patient expired on 23Jan2022 (1 month, 16 days after vaccination). The reported cause of death was Bowel infarction. An autopsy was not performed. The medical history of Femoropopliteal Artery Occlusion, Hypertension, Arterial Stenosis and Ischemic Heart Disease, which contributes to arterial vasoconstriction, remain as confounders for the events mesenteric arterial occlusion and intestinal infarction. The medical history of being Overweight and Smoking, which are risk factors for thromboembol	
[redacted]	GERMANY	Ataxia, Confusional state, Pyrexia, Urosepsis	79.00	Male	Asthma(C); Hyperchromic anaemia(C); Type 2 diabetes mellitus(C); Cardiac failure(C); Hepatic cirrhosis(C)	0	This case was received via European Medicines Agency (Reference number: [redacted] on 01-Mar-2022 and was forwarded to Moderna on 01-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of UROSEPSIS (Ataxia, confusion, disorientation, urosepsis), ATAXIA (Ataxia, confusion, disorientation, urosepsis) and CONFUSIONAL STATE (Ataxia, confusion, disorientation, urosepsis) in a 79-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 216045) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Asthma bronchial (CHILD A), Macrocytic hyperchromic anemia (CHILD A), Type 2 diabetes mellitus (CHILD A), Cardiac insufficiency (CHILD A) and Hepatic cirrhosis (CHILD A). On 20-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 21-Jan-2022, the patient experienced PYREXIA (Ataxia, confusion, disorientation, urosepsis), ATAXIA (Ataxia, confusion, disorientation, urosepsis) (seriousness criterion hospitalization) and CONFUSIONAL STATE (Ataxia, confusion, disorientation,	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							urosepsis) (seriousness criterion hospitalization). On 25-Jan-2022, the patient experienced UROSEPSIS (Ataxia, confusion, disorientation, urosepsis) (seriousness criteria death and hospitalization). The patient died on 25-Jan-2022. The reported cause of death was 10048709. It is unknown if an autopsy was performed. At the time of death, PYREXIA (Ataxia, confusion, disorientation, urosepsis), ATAXIA (Ataxia, confusion, disorientation, urosepsis) and CONFUSIONAL STATE (Ataxia, confusion, disorientation, urosepsis) had not resolved. Patients' medical history included hay fever, chronic heart failure NYHA I. Booster vaccination Spikevax, after previous primary immunization with Comirnaty. Development of confusion 5 hours after vaccination. During the night restlessness, ataxia. By Emergency Medical Order from Tavor. Further neurological deterioration the following day. Arrival of the family doctor in the afternoon. 40.1°C, pronounced state of confusion, ataxia, lack of trunk stability. There was antibiotic treatment for urosepsis, without ultimate stabilization. Patient died after five days. Previously stable general condition. Asthma, type 2 diabetes, and CHILD A liver cirrhosis were known but did not result in any restrictions. The rapid deterioration is at least partly attributable to the high probability of boosting. The internal medicine colleagues confirm the same in the final report. Most recent FOLLOW-UP information incorporated above includes: On 10-Mar-2022: Follow up received included no new information.	
[redacted]	ITALY	Ventricular fibrillation	78.00	Female	Acute coronary syndrome(H); Arteriosclerosis(H)	0	This case was received via European Medicines Agency (Reference number [redacted] on 02-Mar-2022 and was forwarded to Moderna on 02-Mar-2022. This regulatory authority case was reported by a physician and describes the occurrence of VENTRICULAR FIBRILLATION (Terminal disease that directly caused death: ventricular fibrillation.) in a 78-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3001941) for COVID-19 vaccination. The patient's past medical history included Acute coronary syndrome (Intermediate Disease: Acute Coronary Syndrome) and Arteriosclerosis (Initial disease: trivasal coronary atherosclerosis.). On 24-Apr-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced VENTRICULAR FIBRILLATION (Terminal disease that directly caused death: ventricular fibrillation.) (seriousness criterion death). The patient died on 26-Apr-2021. It is unknown if an autopsy was performed.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. No treatment information was provided. Company Comment: This regulatory authority report concerns a 78-year-old, female patient with a medical history of trivasal coronary atherosclerosis and acute coronary syndrome, who experienced the unexpected serious (Results in death) AESI of Ventricular fibrillation. The event occurred unknown number of days after a dose of mRNA-1273 VACCINE, dose number unknown. The event was reported as the "terminal disease that directly caused death", had a fatal outcome. It is unknown whether an autopsy was performed. The patient's age and medical history of trivasal coronary atherosclerosis and acute coronary syndrome, remain as confounders. The benefit-risk relationship of m mRNA-1273 VACCINE is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 16-Jun-2022: Follow up received included no new information.	
[redacted]	TAIWAN, PROVINCE OF CHINA	Headache	65.00	Male	Diabetes mellitus(C)	0	This regulatory authority case was reported by an other health care professional and describes the occurrence of HEADACHE (Headache) in a 65-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 006K21A_1110214-CDC) for COVID-19 vaccination. Concurrent medical conditions included Diabetes. On 27-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to .25 milliliter. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 27-Jan-2022, the patient experienced HEADACHE (Headache) (seriousness criterion death). The patient died in February 2022. The reported cause of death was Headache and psychogenic shock. An autopsy was performed, but no results were provided. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Autopsy: psychogenic shock (abnormal) psychogenic shock. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.	[redacted]

Case ID	Country	ALL PT'S	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Narrative (Complete)	WW Identifier
							No concomitant medication information was provided. It was reported that patient was received two doses of Moderna vaccine and received a dose of Moderna booster at on 27-Jan-2022. After vaccination, patient had severe headache and went to a Neurology Department of clinic. He was scheduled to have further examination in the hospital on 9-Feb-2022, but on 8-Feb-2022, he had shock at the workplace. After forensic examination, it was judged to be psychogenic shock, but patient had only diabetes and did not have heart related diseases. WWID was reported as [redacted] No treatment medication information was provided. Company Comment: This regulatory case concerns a 65-year-old, male patient with no reported relevant medical history, who experienced the unexpected, fatal event of Headache. The patient was reported to have complained of severe headache on the same day after receiving booster dose of mRNA-1273. He then sought medical consult at a neurology clinic where he was given unspecified medication and was scheduled at a later date for further examination. Twelve days after vaccination, the patient suddenly collapsed while at work, experienced shock and died. The clinical course leading to demise were not provided in the case. Post-mortem examination reportedly identified psychogenic shock as cause of death. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event's seriousness was assessed as per Regulatory Authority's report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Significant follow up received updated lab details and narrative.	
[redacted]	SWITZERLAND	Death, Extensive swelling of vaccinated limb, Pneumonitis	95.00	Female	Diabetes mellitus(C); Dementia Alzheimer's type(C); Normochromic normocytic anaemia(C); Chronic kidney disease(C); Cardiomyopathy(C); Hypertension(C); Dyslipidaemia(C); Femur fracture(H)	NOVALGINA; CLEXANE; SEQUASE; CANDESARTAN TAKEDA; CONCOR; DULOXETIN MEPHA; METFORMIN-MEPHA; RISPERIDON MEPHA; TRAJENTA; RYZODEG	This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (Death), EXTENSIVE SWELLING OF VACCINATED LIMB (Extensive swelling of vaccinated limb) and PNEUMONITIS (Pneumonitis) in a 95-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. The patient's past medical history included Femur fracture on 15-Nov-2021. Concurrent medical conditions included Diabetes, Dementia Alzheimer's type, Normochromic normocytic anaemia, Chronic renal failure, Cardiomyopathy (Rhythmogenic and hypertensive cardiopathy in sinus arrest with ventricular escape rhythm) in 2015, Arterial hypertension and Dyslipidaemia. Concomitant products included METAMIZOLE SODIUM (NOVALGINA), ENOXAPARIN SODIUM (CLEXANE), QUETIAPINE FUMARATE (SEQUASE), CANDESARTAN CILEXETIL (CANDESARTAN TAKEDA), BISOPROLOL FUMARATE (CONCOR), DULOXETINE HYDROCHLORIDE (DULOXETIN MEPHA), METFORMIN HYDROCHLORIDE (METFORMIN-MEPHA), RISPERIDONE (RISPERIDON	[redacted]