

Subject ID	MCN
US3552191	(b) (6)
Preferred Term(s):	Dyspnoea exertional Oedema peripheral
Treatment Assignment:	mRNA-1273
Relationship	Related per PI Not-related per Company
Baseline SARS-CoV-2	Negative

A female participant in her 60s experienced dyspnoea exertional Day 8 post Dose 2 and oedema peripheral (bilateral ankle edema) Day 14 post Dose 2. The participant's medical history included breast cancer, diabetes mellitus type 2, hypercholesterolemia, obstructive sleep apnea, hypertension, and depression with anxiety. Participant notified the site of her shortness of breath on exertion, fatigue, and swollen ankles, which resulted in an illness visit in the patient's home, per study procedures. A COVID-19 nasopharyngeal swab was collected, and the result was negative. The following day, participant presented to the Emergency Department after reporting that she could not talk much without feeling winded. Presenting vital signs included temperature 35.6 degrees Celsius temporal and 36.8 degrees Celsius oral, pulse rate 74 bpm, respiratory rate 18 breaths per minute, blood pressure 128/62 mmHg, and oxygen saturation 99%. An electrocardiogram showed sinus tachycardia with no evidence of injury pattern. A chest x-ray revealed no active disease, noting clear lungs and a cardiac silhouette within normal limits showing no evidence of failure. A computerized tomogram of the chest showed no evidence of pulmonary embolism, clear lungs, and mild cardiomegaly. She was admitted overnight. Treatment included a single dose of intravenous furosemide. The following day, the participant was discharged after stating that she felt a little improved. A follow-up with cardiology included an echocardiogram which was negative. Action taken with study drug was not applicable, as the participant had already received both scheduled doses per protocol. The events, bilateral ankle edema and shortness of breath on exertion was considered resolving.

Subject ID	MCN
US3602030	(b) (6)
Preferred Term:	Swelling face, Paraesthesia, Immunisation anxiety related reaction, Feeling hot, Hemiparaesthesia, and Pleuritic pain
Treatment Assignment:	Placebo
Relationship	Related per PI Not-related per Company
Baseline SARS-CoV-2	Negative

A female participant in her 40s experienced swelling face, paraesthesia and immunisation anxiety related reaction Day 7 post Dose 1. The participant's medical history included asthma, root canal, endometriosis, hypertension, acid reflux, hyperlipidemia, left knee osteoarthritis, and multiple sinus surgeries. The symptoms were described as swelling to the right side of the face, tingling on right side of face, and anxiety related to the vaccine. Additionally, the participant had pain chewing on her back teeth due to prior root canal. The participant had an ENT consultation for the discomfort and swelling in her face. The ENT did not find a clear explanation for the findings but suspected an odontogenic infection and referred the participant to an oral surgeon and recommended a sinus computerized tomography scan (CT). She never underwent the CT but did see an oral surgeon who thought her pain might be caused by an issue related to a dental crown at the same site. On Day 17, events of face swelling and paraesthesia resolved, and the participant experienced pleuritic pain described as left-sided back pain, thoracic, and pleuritic chest pain. She was evaluated by a cardiology and primary care and had a negative stress test, normal chest x-ray, and an echocardiogram with normal size of left ventricle cavity, normal global wall motion, visual ejection fraction 55-60-%, doppler evidence of grade 1 (impaired), diastolic dysfunction and structurally normal trileaflet aortic valve with mild grade 1 regurgitation. During the cardiac work-up she experienced left sided chest wall warmth and left sided tingling which occurred Day 26 after Dose 1. Study drug dose was delayed in response to the events of feeling hot and hemiparaesthesia. The event of swelling face recovered on Day 17. The event of paraesthesia recovered on Day 18. The event of pleuritic pain recovered on Day 19. The event of immunisation anxiety related reaction recovered on Day 27. The events of Feeling hot and hemiparaesthesia recovered on Day 36.

Subject ID	MCN
US3552232	(b) (6)
Preferred Terms:	Respiratory failure Acute myocardial infarction, Atrial fibrillation, Hypomagnesaemia, Acute kidney injury, and Organising pneumonia
Treatment Assignment:	Placebo
Relationship	Related per PI Not-related per Company
Baseline SARS-CoV-2	Negative

A male participant in his 70s with medical history of coronary artery disease with myocardial infarction and stent placement, pulmonary embolism, hypertension, hyperlipidemia and type 2 diabetes was hospitalized with acute myocardial infarction, atrial fibrillation, hypomagnesaemia, acute kidney injury, and organising pneumonia Day 29 post Dose 1 and respiratory failure Day 31 post Dose 1. The participant was discharged from the hospital. The event, cryptogenic organizing pneumonia, was reported as resolved with sequelae, the participant completed the antibiotic trials, but remained on home oxygen, which was being weaned. Study drug was discontinued in response to the events of respiratory failure, acute myocardial infarction, hypomagnesaemia, and acute kidney injury. The event of acute myocardial infarction recovered on Day 29. The events of organising pneumonia, hypomagnesaemia, and acute kidney injury recovered on Day 41. The event of respiratory failure recovered on Day 50. The event of atrial fibrillation recovered on Day 63.

Subject ID	MCN
US3912241	(b) (6)
Preferred Terms:	Pulmonary embolism
Treatment Assignment:	Placebo
Relationship	Related per PI Not-related per Company
Baseline SARS-CoV-2	Negative

A male participant in his 50s with obesity and current half pack per day smoking history experience chest pain Day 24 post Dose 1 and called EMS. At the hospital, a computed tomography with angiography of the chest showed a segmental pulmonary embolism of the left lower lobe and mild interstitial pulmonary edema. Treatment for the event included subcutaneous enoxaparin sodium and intravenous ketorolac tromethamine for chest pain. The participant was discharged from the hospital with vital signs including pulse oximetry 94% on room air, blood pressure 146/80 mmHg, temperature 99.3 degrees Fahrenheit, pulse 84 beats per minute, and respiratory rate 16 breaths per minute. Treatment prescribed upon discharge included oral apixaban and oral paracetamol/codeine for chest pain. Study drug was discontinued in response to the event. The event was ongoing at the time of the data cut.

Subject ID	MCN
US3602051	(b) (6)
Preferred Term(s):	Aortic stenosis Procedural haemorrhage
Treatment Assignment:	Placebo
Relationship	Related per PI Not-related per Company
Baseline SARS-CoV-2	Negative

A male participant in his 50s with a medical history of aortic stenosis, chronic obstructive pulmonary disease, hyperlipidemia, smoking, and recurrent syncope experienced worsening of aortic stenosis Day 15 post Dose 2 and procedural haemorrhage Day 16 after Dose 2. The participant experienced worsening of aortic stenosis and was admitted to the hospital. He spent 2 days in the intensive care unit. The participant underwent AVR and was noted to bleed profusely. No action was taken with the study vaccine as he had received both doses per protocol. The event of procedural haemorrhage recovered on Day 42 and aortic stenosis Day 46.

Subject ID	MCN
US3822043	(b) (6)
Preferred Terms:	B-cell small lymphocytic lymphoma
Treatment Assignment:	mRNA-1273
Relationship	Related per PI Not-related per Company
Baseline SARS-CoV-2	Negative

A female participant in her 70s with a medical history of chronic obstructive lung disease, hypertension, and hyperlipidemia had B-cell small lymphocytic lymphoma diagnosed after a routine computed tomography (CT) scan on Day 35 post Dose 2. The participant was scheduled for routine CT of the chest to screen for lung cancer. The CT revealed new (since 26 Jun 2018) enlarged left axillary lymph nodes; stable 11mm part solid nodule in the right upper lobe, unchanged since 26 Jun 2018. Due to the findings, the participant was scheduled for an ultrasound guided biopsy. A biopsy revealed partial involvement by small lymphocytic lymphoma/chronic lymphocytic leukemia. No action was taken with the study vaccine as she had received both doses per protocol. The event was ongoing at the time of the data cut.

Subject ID	MCN
US3432023	(b) (6)
Preferred Term:	Polymyalgia Rheumatica
Treatment Assignment:	Placebo
Relationship	Related
Baseline SARS-CoV-2	Negative

A male participant in his 80s with multiple comorbidities including chronic kidney disease, hypothyroidism, monoclonal gammopathy of undetermined significance (MGUS), and chronic low back pain also taking rosuvastatin 40 milligrams once a day started to develop mild back pain a few days prior to study drug administration. On Day 16 post Dose 1, the participant presented to the emergency room and was hospitalized due to three-day history of severe myalgias, and generalized weakness. Polymyalgia rheumatica was diagnosed. The study vaccine was discontinued in response to the event. The event was ongoing at the time of the data cut, and the participant's symptoms were responsive to out-patient prednisone treatment.

Subject ID	MCN
US3552053	(b) (6)
Preferred Terms:	Nausea Vomiting (Intractable)
Treatment Assignment:	mRNA-1273
Relationship	Related
Baseline SARS-CoV-2	Negative

A female participant in her 60s experienced transient fever and headache following the second dose of study drug, which evolved to include nausea and vomiting requiring hospitalization Day 3 following Dose 2. No action was taken with the study vaccine as she had received both doses per protocol. The event resolved after 7 days (day 35). The discharge summary did not provide an etiology for the nausea and vomiting, but the participant's husband reported that her medical history included headaches with nausea that led to hospitalization in the past.

Subject ID	MCN
US3742169	(b) (6)
Preferred Term:	Rheumatoid arthritis
Treatment Assignment:	mRNA-1273
Relationship	Related
Baseline SARS-CoV-2	Negative

A male participant in his 50s with a past medical history of hypothyroidism, prior hip pain and asthma reported muscle and joint aches/pain in the e-diary on the same day as Dose 1. Approximately 10 days post Dose 1, the participant experienced recurrent muscle joint aches/pain. The quality of the pain was different than the joint aches/pain previously reported, with the left knee and right shoulder bothering him the most. Approximately 29 days post dose 1, the participant saw a rheumatologist who noted a high level of CCP antibody and rheumatoid factor and diagnoses included rheumatoid arthritis and lateral epicondylitis. One month later, the participant began treatment with oral meloxicam. Dosing with the study vaccine was discontinued in response to the event. The event was ongoing at the time of the data cut.

Subject ID	MCN
US3322329	(b) (6)
Preferred Term:	Swelling face
Treatment Assignment:	mRNA-1273
Relationship	Related
Baseline SARS-CoV-2	Negative

A female participant in her 50s experienced face swelling Day 3 post dose 2. Eleven days prior to Dose 2, the participant had cosmetic injections in her cheeks. She was injected with a Botox/Filler combination consisting of 60 units of BOTOX Cosmetic, 1 unit of Juvederm Ultra Plus XC, and 3 units of Juvederm Voluma subcutaneous. The participant presented to the site for her Dose 2 visit and her physical examination was normal, including a skin assessment. Four days post dose 2, the participant developed injection site swelling/ hardness measuring 125 mm with mild deltoid tenderness at the site of study drug administration, but denied trouble moving the affected arm. That night, she experienced bilateral facial swelling, which was greater on the left side than the right. The subject contacted the doctor that performed the cosmetic procedure concerning her moderate facial swelling and was prescribed a five-day course of oral prednisolone (initial dose of 25 mg, followed by 40 mg daily) as treatment. Concomitant medications reported included estradiol, testosterone and naproxen. Botox Cosmetic, Juvederm Ultra Plus XC and Juvederm Voluma subcutaneous were reported by the Investigator as co-suspect products. No action was taken with the study vaccine as she had received both doses per protocol. The event resolved 7 days later.

Subject ID	MCN
US3542108	(b) (6)
Preferred Term:	Swelling face
Treatment Assignment:	mRNA-1273
Relationship	Related
Baseline SARS-CoV-2	Negative

A female participant in her 40s experienced bilateral face swelling 1 Day post Dose 2. Prior to enrolling in the study (5 months), the subject had bilateral Voluma (hyaluronic acid) cheek injections. Participant woke up with significant bilateral cheek swelling; no rash, pain, tenderness, oral or respiratory symptoms. She had no fever or chills and felt well aside from unsightly cheek swelling. She had no new medications, foods, creams, toothpaste, etc. Treatment started with oral diphenhydramine 50 mg daily which was then advance to oral methylprednisolone 4 mg tabs. The swelling resolved 6 days later, and the participant had no recurrence.

Subject ID	MCN
US3512042	(b) (6)
Preferred Term:	Cardio-respiratory Arrest
Treatment Assignment:	mRNA-1273
Relationship	Not Related
Baseline SARS-CoV-2	Negative

A male participant in his 70s experienced Cardio-respiratory arrest on Day 21 after Dose 1 resulting in death. He was found by his wife after passing away at home. The cause of death was cardiopulmonary arrest due to hypertension/hyperlipidemia. Past medical history also included paroxysmal atrial fibrillation, and ocular thrombosis. The event was considered not related.

Subject ID	MCN
US3872318	(b) (6)
Preferred Term:	Completed Suicide
Treatment Assignment:	mRNA-1273
Relationship	Not Related
Baseline SARS-CoV-2	Negative

A male participant in his 60s completed suicide on Day 21 after Dose 1. The participant's medical history included suicidal thoughts in response to separation from his wife, and depression. The participant's son had reported that he believed that his father had an obsessive concern about being diagnosed with cancer, suffered from depression and may have thought about suicide before. The event was considered not related.

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Subject ID	MCN
US3962094	(b) (6)
Preferred Term:	Head Injury
Treatment Assignment:	mRNA-1273
Relationship	Not Related
Baseline SARS-CoV-2	Negative

A female participant in her 50s died of head injury on Day 37 after Dose 1. The site made several unsuccessful attempts to contact the participant, her sister contacted the police for a wellness check. The participant was found deceased on the bathroom floor. The event was considered not related.

Subject ID	MCN
US3752173	(b) (6)
Preferred Term:	Myocardial Infarction
Treatment Assignment:	mRNA-1273
Relationship	Not Related
Baseline SARS-CoV-2	Negative

A male participant in his 70s experienced a myocardial infarction on Day 45 after Dose 2. The participant died on Day 73. The cause of death was “massive heart attack”. No further information was provided. Medical history included prior myocardial infarction and chronic obstructive pulmonary disease. The event was considered not related.

Subject ID	MCN
US3432295	(b) (6)
Preferred Terms:	Systemic Inflammatory Response Syndrome Dermatitis Bullous
Treatment Assignment:	Placebo
Relationship	Not Related
Baseline SARS-CoV-2	Negative

A male participant in his 80s experienced dermatitis bullous on Day 18 post Dose 1 and systemic inflammatory response syndrome on Day 36 after Dose 1. The participant was diagnosed with CLL in Dec 2019. The month prior to study drug administration, the participant began to experience new symptoms consistent with CLL progression, including night sweats and fatigue. A positron emission tomography with computerized tomography (PET-CT) scan was performed 12 days prior to first dose to further evaluate these symptoms and their potential relationship to disease transformation. Primary findings included uptake/avidity at the left base of the tongue, the posterior right greater trochanter, the right humeral head, the right femoral head, the left femoroacetabular joint space, and the right axillary lymph nodes, which were noted by the radiologist as atypical for squamous cell carcinoma metastasis and more compatible with lymphoma. Splenomegaly (16 cm along the craniocaudal axis) was also observed. The participant died on Day 37. Per autopsy report, the cause of death was severe systemic inflammatory syndrome in the setting of CLL. The event was considered not related.

Subject ID	MCN
US3272070	(b) (6)
Preferred Term:	Myocardial Infarction
Treatment Assignment:	Placebo
Relationship	Not Related
Baseline SARS-CoV-2	Negative

A male participant in his 70s experienced a myocardial infarction on Day 29 after Dose 2. The participant presented via emergency medical services as a cardiac arrest. The participant died on Day 56 (28 days from last dose). The cause of death was myocardial infarction. The participant's medical history included diabetes mellitus type 2, hypertension, hypercholesterolemia, and chronic obstructive pulmonary disease. The event was considered not related.

Subject ID	MCN
US3082269	(b) (6)
Preferred Term:	Abdominal Injury (Intra-abdominal perforation)
Treatment Assignment:	Placebo
Relationship	Not Related
Baseline SARS-CoV-2	Negative

A male participant in his 70s experienced abdominal injury due to pneumoperitoneum and presumed intra-abdominal perforation on Day 12 after Dose 1. The participant initially complained of abdominal pain and dyspnea and went to his primary care physician's (PCP) office he was found to have uncontrolled atrial fibrillation (A-fib), hypoxia with pulse oxygen of 45%, and hypotension. participant was transported to the hospital where he was hypotensive, dyspneic and had A-fib with rapid ventricular rate and ventricular arrhythmia. The event was considered not related. The cause of death was pneumoperitoneum, presumed intra-abdominal perforation that led to cardiac arrest. The event was considered not related.

Subject ID	MCN
US3342256	(b) (6)
Preferred Term:	Cardio-respiratory Arrest
Treatment Assignment:	Placebo
Relationship	Not Related
Baseline SARS-CoV-2	Negative

A male participant in his 40s with a medical history included heart disease and gastric sleeve surgery, experienced cardio-respiratory arrest Day 7 after Dose 1. The participant's spouse called the site to inform site staff of the participant's passing; she stated that the participant had a history of heart disease. No further information was provided. The event was considered not related.