

Mfr Report #	(b) (6)
UF/Importer Report #	
FDA Use Only	

A. PATIENT INFORMATION			
1. Patient Identifier US3552232	2. Age at Time of Event: 70 Years or Date of Birth: (b) (6)/1950	3. Sex <input type="checkbox"/> Female <input checked="" type="checkbox"/> Male	4. Weight ____ lbs or ____ kgs
In confidence			
B. ADVERSE EVENT OR PRODUCT PROBLEM			
1. <input checked="" type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product Problem (e.g., defects/malfunctions)			
2. Outcomes Attributed to Adverse Event (Check all that apply)			
<input type="checkbox"/> Death: _____ (mm/dd/yyyy) <input type="checkbox"/> Disability or Permanent Damage <input type="checkbox"/> Life-threatening _____ (mm/dd/yyyy) <input type="checkbox"/> Congenital Anomaly/Birth Defect <input checked="" type="checkbox"/> Hospitalization - initial or prolonged <input type="checkbox"/> Other Serious (Important Medical Events) <input type="checkbox"/> Required Intervention to Prevent Permanent Impairment/Damage (Devices)			
3. Date of Event (mm/dd/yyyy) 09/26/2020		4. Date of This Report (mm/dd/yyyy) 11/22/2020	
5. Describe Event or Problem Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) PAROXYSMAL ATRIAL FIBRILLATION [Paroxysmal atrial fibrillation] CRYPTOGENIC ORGANIZING PNEUMONIA [Cryptogenic organizing pneumonia] RESPIRATORY FAILURE [Respiratory failure] NON-ST ELEVATED MYOCARDIAL INFARCTION [Non ST segment elevation myocardial infarction] HYPOMAGNESIA [Hypomagnesemia] ACUTE KIDNEY INJURY [Acute kidney injury]			
Case Description: Cohort: >=65 years Date of Birth: 1950 (b) (6) AE: CRYPTOGENIC ORGANIZING PNEUMONIA continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates #1 09/27/2020 Blood albumin (continued) #2 10/16/2020 Blood albumin (continued) #3 09/30/2020 Blood calcium (continued) #4 10/06/2020 Blood calcium (continued) #5 10/16/2020 Blood calcium (continued) #6 09/29/2020 Blood chloride (continued) continued in additional info section...			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) Race: White #1 --/--/1951 to Ongoing Current Condition, (Continued) #2 --/--/1951 to Ongoing Historical Condition, (Continued) #3 --/--/1975 to --/--/1975 Historical Condition, (Continued) continued in additional info section...			

C. SUSPECT PRODUCT(S)			
1. Name (Give labeled strength & mfr/labeler)			
#1. mRNA-1273 vs Placebo (Code not broken)			
#2.			
2. Dose, Frequency & Route Used		3. Therapy Dates (if unknown, give duration) from/to (or best estimate)	
#1. Blinded, Information withheld.		#1. 08/29/2020 to 08/29/2020	
#2.		#2.	
4. Diagnosis for Use (Indication)		5. Event Abated After Use Stopped or Dose Reduced?	
#1. COVID-19 (Continued)		#1. <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply	
#2.		#2. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply	
6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?	
#1. Blinded	#1. Blinded	#1. <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Doesn't Apply	
#2.	#2.	#2. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply	
9. NDC# or Unique ID			
10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)			
1) ASPIRIN /00002701/ (ASPIRIN /00002701/) --/--/2013 continued in additional info section...			
G. ALL MANUFACTURERS			
1. Contact Office (and Manufacturing Site for Devices)		2. Phone Number	
Name ModernaTX, Inc. David Martin MD.		617-335-1804	
Address 200 Technology Square Cambridge, MA 02139 United States of America		3. Report Source (Check all that apply)	
Email Address		<input type="checkbox"/> Foreign <input checked="" type="checkbox"/> Study <input type="checkbox"/> Literature <input type="checkbox"/> Consumer <input checked="" type="checkbox"/> Health Professional <input type="checkbox"/> User Facility <input type="checkbox"/> Company Representative <input type="checkbox"/> Distributor <input type="checkbox"/> Other: _____	
4. Date Received by Manufacturer (mm/dd/yyyy) 11/19/2020	5. (A)NDA # IND # 019635 BLA # PMA/ 510(k) # Combination Product <input type="checkbox"/> Yes Pre-1938 <input type="checkbox"/> Yes OTC Product <input type="checkbox"/> Yes		
6. If IND, Give Protocol # mRNA-1273-P301	7. Type of Report (Check all that apply) <input type="checkbox"/> 5-day <input type="checkbox"/> 30-day <input type="checkbox"/> 7-day <input type="checkbox"/> Periodic <input type="checkbox"/> 10-day <input type="checkbox"/> Initial <input type="checkbox"/> 15-day <input checked="" type="checkbox"/> Follow-up #6		
9. Manufacturer Report Number (b) (6)		8. Adverse Event Term(s) Paroxysmal atrial fibrillation, Cryptogenic organizing pneumonia, Respiratory continued in additional info section...	
E. INITIAL REPORTER			
1. Name and Address Dr. SHARON FREY Saint Louis University Saint Louis, MO UNITED STATES			
Phone # (b) (6)		Email Address (b) (6) @health.slu.edu	
2. Health Professional? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	3. Occupation Physician	4. Initial Reporter Also Sent Report to FDA <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Unk	

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event

ADDITIONAL INFORMATION**B5. EVENT DESCRIPTION (Continued)**

Start Date: 20200926

SAE Description: SUBJECT CONTACTED SITE ON 9/25 WITH ALLERGY SYMPTOMS (SNIFFLES, POST NASAL DRAINAGE COUGH) TYPICAL TO SUBJECT PER SUBJECT; INSTRUCTED TO CALL BACK IF ANYTHING WORSENS OR CHANGES. PER SUBJECT 9/26 WORSENING COUGH AND FEVER OF 101. ILLNESS VISIT SCHEDULED 9/28, SUBJECT URGED TO CONTACT PCP OR URGENT CARE. PER SUBJECT 9/28, ADMITTED TO THE HOSPITAL ON 9/26, HAD A NEGATIVE COVID-19 SWAB AND ONGOING COUGH AND FEVER WITH CARDIOLOGY WORKUP. PER INPATIENT ID PHYSICIAN STATED SUBJECT HAS PNEUMONIA AND RESPIRATORY FAILURE WITH CHEST X-RAY SUGGESTIVE OF COVID-19 AND IS ON 6L OF O2. 9/29 UPDATE: CONDITION WORSENING; SUBJECT ON 8L/MIN O2; DIFFUSE BILAT INFILTRATES, POSSIBLY ORGANIZING PNEUMONIA; BRONCHOSCOPY PLANNED, HAS HAD 2 NEG COVID TESTS. SUBJECT'S BRONCHOSCOPY ALSO NEGATIVE FOR COVID, WEANED TO 3L, REMAINS INPATIENT, CULTURES ARE STILL PENDING FROM BRONCH. BEING FOLLOWED BY CARDS, PULM, AND ID, ON STEROIDS.

UPDATE 10/12: SUBJECT DISCHARGED 10/8 ON 2L O2. DIAGNOSED WITH NSTEMI ON ADMISSION IN NEW ONSET AFIB; HOLTER MONITOR ON DISCHARGE FOR 30 DAYS. ECHO SHOWS EF OF 35-45% AT DISCHARGE. TROPONINS ELEVATED ON ADMISSION, SECONDARY TO ISCHEMIA RELATED TO AFIB PER RECORDS. CHEST X RAYS (9/26 & 10/6) SHOW BILAT INFILTRATES/MULTIFOCAL PNEUMONIA; CHEST CT WITH SAME FINDINGS - FINAL DIAGNOSIS OF CRYPTOGENIC ORGANIZING PNEUMONIA, REMAINS ON PREDNISONE. NEGATIVE RESPIRATORY PANEL. BRONCHOSCOPY 9/30, CULTURES OBTAINED BUT RESULTS NOT IN RECORDS. PER SUBJECT REPORT AS OF 10/12, NOW ON 4L O2. SUBJECT READMITTED FOR ATRIAL FIBRILLATION ON 10/15-10/17; X RAY ON 10/15 SHOWED PNEUMONIA ONGOING. UPDATE 10/30/20: SUBJECT REPORTED TO CLINIC FOR DAY 57 VISIT; O2 IS DOWN TO 1L/MIN WHILE UP AND ABOUT; PNEUMONIA AND COUGH IMPROVE.

Requires inpatient or prolongation of existing Hospitalization: Yes

Action Taken: None

Action Taken ER Visit: 1

Related to procedure: Not Related

Severity: Grade 4

Date of hospital admission: 20200926

Date of hospital discharge: 20201008

Admitted to ICU?: No

Outcome, specify: SUBJECT HAS COMPLETED HIS ANTIBIOTIC TRIALS, BUT REMAINS ON HOME OXYGEN THAT IS BEING WEANED. CURRENTLY ON 1L NC.

AE: RESPIRATORY FAILURE

Start Date: 20200928

SAE Description: SUBJECT CONTACTED SITE ON 9/25 WITH ALLERGY SYMPTOMS (SNIFFLES, POST NASAL DRAINAGE COUGH) TYPICAL TO SUBJECT PER SUBJECT; INSTRUCTED TO CALL BACK IF ANYTHING WORSENS OR CHANGES. PER SUBJECT 9/26 WORSENING COUGH AND FEVER OF 101. ILLNESS VISIT SCHEDULED 9/28, SUBJECT URGED TO CONTACT PCP OR URGENT CARE. PER SUBJECT 9/28, ADMITTED TO THE HOSPITAL ON 9/26, HAD A NEGATIVE COVID-19 SWAB AND ONGOING COUGH AND FEVER WITH CARDIOLOGY WORKUP. PER INPATIENT ID PHYSICIAN STATED SUBJECT HAS PNEUMONIA AND RESPIRATORY FAILURE WITH CHEST X-RAY SUGGESTIVE OF COVID-19 AND IS ON 6L OF O2. 9/29 UPDATE: CONDITION WORSENING; SUBJECT ON 8L/MIN O2; DIFFUSE BILAT INFILTRATES, POSSIBLY ORGANIZING PNEUMONIA; BRONCHOSCOPY PLANNED, HAS HAD 2 NEG COVID TESTS. SUBJECT'S BRONCHOSCOPY ALSO NEGATIVE FOR COVID, WEANED TO 3L, REMAINS INPATIENT, CULTURES ARE STILL PENDING FROM BRONCH. BEING FOLLOWED BY CARDS, PULM, AND ID, ON STEROIDS.

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Requires inpatient or prolongation of existing Hospitalization: Yes

Action Taken: Investigational Product Withdrawn

Action Taken ER Visit: 1

Related to procedure: Not Related

Severity: Grade 4

Date of hospital admission: 20200926

Date of hospital discharge: 20201008

Admitted to ICU?: No

AE: PAROXYSMAL ATRIAL FIBRILLATION

Start Date: 20200926

SAE Description: SUBJECT CONTACTED SITE ON 9/25 WITH ALLERGY SYMPTOMS (SNIFFLES, POST NASAL DRAINAGE COUGH) TYPICAL TO SUBJECT PER SUBJECT; INSTRUCTED TO CALL BACK IF ANYTHING WORSENS OR CHANGES. PER SUBJECT 9/26 WORSENING COUGH AND FEVER OF 101. ILLNESS VISIT SCHEDULED 9/28, SUBJECT URGED TO CONTACT PCP OR URGENT CARE. PER SUBJECT 9/28, ADMITTED TO THE HOSPITAL ON 9/26, HAD A NEGATIVE COVID-19 SWAB AND ONGOING COUGH AND FEVER WITH CARDIOLOGY WORKUP. PER INPATIENT ID PHYSICIAN STATED SUBJECT HAS PNEUMONIA AND RESPIRATORY FAILURE WITH CHEST X-RAY SUGGESTIVE OF COVID-19 AND IS ON 6L OF O2. 9/29 UPDATE: CONDITION WORSENING; SUBJECT ON 8L/MIN O2; DIFFUSE BILAT INFILTRATES, POSSIBLY ORGANIZING PNEUMONIA; BRONCHOSCOPY PLANNED, HAS HAD 2 NEG COVID TESTS. SUBJECT'S BRONCHOSCOPY ALSO NEGATIVE FOR COVID, WEANED TO 3L, REMAINS INPATIENT, CULTURES ARE STILL PENDING FROM BRONCH. BEING FOLLOWED BY CARDS, PULM, AND ID, ON STEROIDS.

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Requires inpatient or prolongation of existing Hospitalization: Yes

Action Taken: None

Action Taken ER Visit: 1

Related to procedure: Not Related

Severity: Grade 4

Date of hospital admission: 20200926

Date of hospital discharge: 20201008

Admitted to ICU?: No

Outcome, specify: SUBJECT IS CURRENTLY IN SINUS RHYTHM, BUT COULD INTERMITTENTLY GO IN AND OUT OF ATRIAL FIBRILLATION. ON MEDICATION AND FOLLOWING UP WITH PCP TO CONTROL AND MONITOR.

AE: NON-ST ELEVATED MYOCARDIAL INFARCTION

Start Date: 20200926

SAE Description: SUBJECT CONTACTED SITE ON 9/25 WITH ALLERGY SYMPTOMS (SNIFFLES, POST NASAL DRAINAGE COUGH) TYPICAL TO SUBJECT PER SUBJECT; INSTRUCTED TO CALL BACK IF ANYTHING WORSENS OR CHANGES. PER SUBJECT 9/26 WORSENING COUGH AND FEVER OF 101. ILLNESS VISIT SCHEDULED 9/28, SUBJECT URGED TO CONTACT PCP OR URGENT CARE. PER SUBJECT 9/28, ADMITTED TO THE HOSPITAL ON 9/26, HAD A NEGATIVE COVID-19 SWAB AND ONGOING COUGH AND FEVER WITH CARDIOLOGY WORKUP. PER INPATIENT ID PHYSICIAN STATED SUBJECT HAS PNEUMONIA AND RESPIRATORY FAILURE WITH CHEST X-RAY SUGGESTIVE OF COVID-19 AND IS ON 6L OF O2. 9/29 UPDATE: CONDITION WORSENING; SUBJECT ON 8L/MIN O2; DIFFUSE BILAT INFILTRATES, POSSIBLY ORGANIZING PNEUMONIA; BRONCHOSCOPY PLANNED, HAS HAD 2 NEG COVID TESTS. SUBJECT'S BRONCHOSCOPY ALSO NEGATIVE FOR COVID, WEANED TO 3L, REMAINS INPATIENT, CULTURES ARE STILL PENDING FROM BRONCH. BEING FOLLOWED BY CARDS, PULM, AND ID, ON STEROIDS.

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Requires inpatient or prolongation of existing Hospitalization: Yes

Action Taken: None

Action Taken ER Visit: 1

Related to procedure: Not Related

Severity: Grade 4

Date of hospital admission: 20200926

Date of hospital discharge: 20201008

Admitted to ICU?: No

AE: HYPOMAGNESIA

Start Date: 20200926

SAE Description: SUBJECT CONTACTED SITE ON 9/25 WITH ALLERGY SYMPTOMS (SNIFFLES, POST NASAL DRAINAGE COUGH) TYPICAL TO SUBJECT PER SUBJECT; INSTRUCTED TO CALL BACK IF ANYTHING WORSENS OR CHANGES. PER SUBJECT 9/26 WORSENING COUGH AND FEVER OF 101. ILLNESS VISIT SCHEDULED 9/28, SUBJECT URGED TO CONTACT PCP OR URGENT CARE. PER SUBJECT 9/28, ADMITTED TO THE HOSPITAL ON 9/26, HAD A NEGATIVE COVID-19 SWAB AND ONGOING COUGH AND FEVER WITH CARDIOLOGY WORKUP. PER INPATIENT ID PHYSICIAN STATED SUBJECT HAS PNEUMONIA AND RESPIRATORY FAILURE WITH CHEST X-RAY SUGGESTIVE OF COVID-19 AND IS ON 6L OF O2. 9/29 UPDATE: CONDITION WORSENING; SUBJECT ON 8L/MIN O2; DIFFUSE BILAT INFILTRATES, POSSIBLY ORGANIZING PNEUMONIA; BRONCHOSCOPY PLANNED, HAS HAD 2 NEG COVID TESTS. SUBJECT'S BRONCHOSCOPY ALSO NEGATIVE FOR COVID, WEANED TO 3L, REMAINS INPATIENT, CULTURES ARE STILL PENDING FROM BRONCH. BEING FOLLOWED BY CARDS, PULM, AND ID, ON STEROIDS.

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Requires inpatient or prolongation of existing Hospitalization: Yes

Action Taken: None

Action Taken ER Visit: 1

Related to procedure: Not Related

Severity: Grade 4

Date of hospital admission: 20200926

Date of hospital discharge: 20201008

Admitted to ICU?: No

AE: ACUTE KIDNEY INJURY

Start Date: 20200926

SAE Description: SUBJECT CONTACTED SITE ON 9/25 WITH ALLERGY SYMPTOMS (SNIFFLES, POST NASAL DRAINAGE COUGH) TYPICAL TO SUBJECT PER SUBJECT; INSTRUCTED TO CALL BACK IF ANYTHING WORSENS OR CHANGES. PER SUBJECT 9/26 WORSENING COUGH AND FEVER OF 101. ILLNESS VISIT SCHEDULED 9/28, SUBJECT URGED TO CONTACT PCP OR URGENT CARE. PER SUBJECT 9/28, ADMITTED TO THE HOSPITAL ON 9/26, HAD A NEGATIVE COVID-19 SWAB AND ONGOING COUGH AND FEVER WITH CARDIOLOGY WORKUP. PER INPATIENT ID PHYSICIAN STATED SUBJECT HAS PNEUMONIA AND RESPIRATORY FAILURE WITH CHEST X-RAY SUGGESTIVE OF COVID-19 AND IS ON 6L OF O2. 9/29 UPDATE: CONDITION WORSENING; SUBJECT ON 8L/MIN O2; DIFFUSE BILAT INFILTRATES, POSSIBLY ORGANIZING PNEUMONIA; BRONCHOSCOPY PLANNED, HAS HAD 2 NEG COVID TESTS. SUBJECT'S BRONCHOSCOPY ALSO NEGATIVE FOR COVID, WEANED TO 3L, REMAINS INPATIENT, CULTURES ARE STILL PENDING FROM BRONCH. BEING FOLLOWED BY CARDS, PULM, AND ID, ON STEROIDS.

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CULTURES OBTAINED BUT RESULTS NOT IN RECORDS. PER SUBJECT REPORT AS OF 10/12, NOW ON 4L O2.

Requires inpatient or prolongation of existing Hospitalization: Yes

Action Taken: None

Action Taken ER Visit: 1

Related to procedure: Not Related

Severity: Grade 4

Date of hospital admission: 20200926

Date of hospital discharge: 20201008

Admitted to ICU?: No

Study Drug iterations first and closest:

Study Drug First Start Date: 20200829

Study Drug First Start Time:

Study Drug Latest Start Date: 20200829

Study Drug Latest Start Time:

This 70-year-old, White, male subject (US3552232) was participating in A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older (mRNA-1273-P301) and experienced cryptogenic organizing pneumonia, respiratory failure, paroxysmal atrial fibrillation, non-ST elevated myocardial infarction, hypomagnesemia, and acute kidney injury.

The subject's medical history, as provided by the investigator, included left lens erosion, type II diabetes, low back pain, right elbow wound, right shoulder dislocation, seasonal allergies, chronic kidney disease, right lower extremity cellulitis, depression, sensory diabetic neuropathy, diverticulosis of colon, gastritis, coronary artery disease, Helicobacter pylori infection, iron deficiency anemia, mitral valve regurgitation, myocardial infarction, adenomatous colon polyp, colonoscopy, tuberculosis exposure, pyuria, pulmonary embolism, coronary artery stent, hypertension, recurrent urinary tract infections, urinary retention, methicillin resistance staphylococcus aureus (MRSA) positive, benign prostatic hypertrophy, insomnia, hyperlipidemia, and diabetic retinopathy left eye. Per discharge summary, additional medical history included angiotensin-converting-enzyme inhibitor allergy (cough), MRSA bacteremia, obesity unspecified, personal history of contact with and (suspected) exposure to lead, prolonged international normalized ratio, cataract removal and septic pulmonary embolism. Concomitant medications reported included aspirin, insulin glargine, trazodone, liraglutide, clopidogrel bisulfate, hydralazine, tamsulosin hydrochloride, finasteride, amlodipine, metformin, and atorvastatin.

The subject was allocated to receive intramuscular mRNA-1273 or placebo for SARS-CoV-2 vaccination. The subject received the first dose of blinded study drug on 29 Aug 2020. The subject's last dose of study drug prior to event onset was on 29 Aug 2020.

On 22 Sep 2020, the subject experienced cough and she took dextromethorphan/chlorpheniramine maleate.

On 25 Sep 2020, the subject reported typical allergy symptoms of sniffles, postnasal drainage and a cough.

He was advised to call back if symptoms worsened or changed. Further reported symptoms included general body aches, headache, chest tightness, and fatigue.

On 26 Sep 2020, the subject experienced worsening cough and fever of 101 degrees Fahrenheit, and pneumonia, new onset paroxysmal atrial fibrillation with rapid ventricular response, non-ST elevated myocardial infarction, hypomagnesemia, fever, and acute kidney injury were diagnosed. On the same day, he was admitted to the hospital. Troponins were elevated on admission, peak 2.415 ng/mL (<0.038), likely secondary to demand ischemia from rapid atrial fibrillation. Further laboratory test results included sodium 135 mmol/L (138-145), carbon dioxide (CO2) 18 mmol/L (23-31), blood urea nitrogen (BUN) 47 mg/dL (8.4-25.7), creatinine (Cr) 2.59 mg/dL (0.72-1.25), glucose 466 mg/dL (70-105), white blood cell count (WBC) 10.8 x 10E9/L (4.4-10.7), red blood cell count (RBC) 3.72 x 10E12/L (3.80-5.40), hemoglobin (Hgb) 11.3 gm/dL (12.0-17.6), and hematocrit (Hct) 33.5% (35.2-51.7), neutrophil 90.5% (44.0-73.0), lymphocytes 2.2% (20.0-43.0), neutrophil absolute 9.75 x 10E9/L (2.01-7.14), lymphocyte absolute 0.24 x 10E9/L (1.07-3.94), magnesium 1.0 mg/dL (1.6-2.6), and procalcitonin 2.76 ng/mL (<0.10). Chest x-ray showed bilateral infiltrates consistent with multifocal pneumonia, which was a pattern suggestive of, but not a diagnostic for, COVID-19 pneumonia. Blood cultures showed one with Staph hominis and the second with no growth, which was considered a likely contaminant. Urine culture revealed <10,000 CFU/mL urogenital flora. Urinalysis revealed color yellow, protein 3+, blood 1+, leukocyte trace, glucose 3+, and WBC greater than 100. Respiratory panel was negative. Initial treatment included ceftriaxone sodium and azithromycin, which were stopped as the diagnosis was likely cryptogenic organizing pneumonia. Treatment for acute kidney injury included intravenous fluids. Further treatment included acetylsalicylic acid, magnesium, enoxaparin sodium, insulin aspart, and dexamethasone.

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On 27 Sep 2020, vital signs included blood pressure (BP) 142/61 mmHg, pulse 96 beats per minute (bpm), respiratory rate 25 breaths per minute (bpm), temperature 98.1 degrees Fahrenheit, and oxygen saturation 76% at 01:56, which improved to 93% at 01:58. Laboratory results included troponin I was 1.643 ng/mL, WBC 14.5 x 10E9/L, RBC 3.63 x 10E12/L, Hgb 11.0 gm/dL, Hct 33.8%, neutrophils 91.0%, lymphocytes 2.7%, neutrophil absolute 13.21 x 10E9/L, lymphocyte absolute 0.38 x 10E9/L, Hgb A1c 9.0% (4.2-5.6), glucose 120 mg/dL, CO2 20 mmol/L, BUN 48 mg/dL, Cr 2.40 mg/dL, total protein 6.2 gm/dL (6.4-8.3), and albumin 3.1 gm/dL (3.2-4.6). Paroxysmal atrial fibrillation was noted. The subject self-converted to sinus rhythm with Bachmann's bundle. COVID-19 nasopharyngeal swab was negative. Treatment included ondansetron for nausea, benzonatate for cough, and acetylsalicylic acid. The subject's type II diabetes was uncontrolled, and his insulin glargine dose was increased.

On 28 Sep 2020, the subject experienced acute hypoxic respiratory failure secondary to bilateral pulmonary infiltrates with ongoing cough and fever of 101 degrees Fahrenheit. Physical exam revealed diminished breath sounds with coarse crackles and lower extremity edema. The subject was treated with 6 liters of oxygen and remained hospitalized. A cardiology workup was done. Echocardiogram showed cardiomyopathy with ejection fraction 30-35%. Chest x-ray showed increasing bilateral patchy airspace consolidation, right greater than left. Ferritin was 334 ng/mL (22-276) and C-reactive protein was 31.37 mg/dL (<=0.50). Treatment included oral levofloxacin.

On 29 Sep 2020, the subject's condition worsened, and he was treated with 8 liters/min of oxygen. Vital signs included BP 171/95 mmHg, pulse 72 bpm, respiratory rate 24, temperature 97.4 degrees Fahrenheit, and oxygen saturation 97%. Laboratory results included chloride (Cl) 110 mmol/L (98-107), CO2 17 mmol/L, BUN 63 mg/dL, Cr 2.25 mg/dL, glucose 160 mg/dL, WBC 20.9 x10E9/L, RBC 3.69 x10E12/L, Hgb 11.2 gm/dL, Hct 34.6%, neutrophils 94.6%, lymphocytes 1.5%, monocytes 2.4%, neutrophil absolute 19.80 x10E9/L, and lymphocytes absolute 0.02 x10E9/L. Computerized tomogram (CT) of chest showed findings in keeping with multifocal pneumonia, no lobe was spared; small bilateral pleural effusions were noted, right greater than left; and esophageal wall thickening, nonspecific was considered to be correlated with esophageal reflux. A follow-up chest CT was recommended after the appropriate course of therapy to document resolution of these findings. Echocardiogram showed left ventricle was normal in size, moderately to markedly reduced systolic left ventricular function, ejection fraction 30-35%, left ventricle wall thickness was normal, no regional wall motion abnormalities, left ventricular diastolic function parameters were normal, and right ventricular systolic pressure was 30 mmHg. Urine Strep pneumoniae and Legionella antigens were negative. Treatment included a course of steroids, hydrocodone/acetaminophen, and dextromethorphan/guaifenesin.

On 30 Sep 2020, the subject underwent a bronchoscopy and cultures were obtained. Bronchoscopy showed unresolved bilateral infiltrates, washings were obtained from endobronchial tree, bronchoalveolar lavage was performed from right upper lobe and right middle lobe, there was no evidence of diffuse alveolar hemorrhage, and culture results were pending. Laboratory results included WBC 15.9 x10E9/L, Hgb 10.1 gm/dL, Hct 30.9%, Cl 111 mmol/L, CO2 20 mmol/L, BUN 56 mg/dL, Cr 1.98 mg/dL, glucose 116 mg/dL, and calcium (Ca) 8.1 mg/dL (8.1-10.4). Bronchial washing gram stain and culture, and bronchoalveolar lavage gram stain showed moderate polymorphonuclear cells and no organisms. Differential from the manual bronchoalveolar lavage showed neutrophil 45%, lymphocytes 73%, macrophage 32%, and cells counted 100. Respiratory panel was negative. The subject was weaned to 3 liters of oxygen. Treatment included salbutamol 0.5%, lidocaine 4%, and levalbuterol.

On 01 Oct 2020, treatment included enoxaparin sodium and diltiazem. Bronchoalveolar lavage culture and gram stain and bronchial washing culture and gram stain showed no growth, moderate polymorphonuclear cells, and no organisms seen. Blood culture showed no growth. Bronchoalveolar lavage pathology smear body fluid revealed no malignancy.

On 02 Oct 2020, Bronchoalveolar lavage culture and gram stain and bronchial washing culture and gram stain showed no growth, moderate polymorphonuclear cells, and no organisms seen. Blood culture showed growth of Staphylococcus hominis, which was possible contaminant unless multiple cultures were positive for the same isolate. Bronchial washing cytology showed no cytological diagnosis and was negative for malignancy. Treatment for pneumonia included oral prednisone.

On 03 Oct 2020, vital signs included blood pressure 159/90 mmHg, pulse 97 bpm, respiratory rate 20, temperature 97.2 degrees Fahrenheit, and oxygen saturation 95%. Physical examination revealed diminished breath sounds with coarse crackles; tachycardia, irregular rhythm, and lower extremity edema.

On 04 Oct 2020, herpes simplex 1+2 polymerase chain reaction was negative.

On 05 Oct 2020, the subject's Foley catheter was removed, and he was able to void. Treatment included digoxin and amiodarone. Bronchoalveolar lavage acid-fast bacilli smear showed no acid-fast bacilli. Fungus culture and smear of bronchial washing showed no fungus isolated, no yeast or hyphae seen, and no Pneumocystis jirovecii.

On 06 Oct 2020, chest x-ray showed bilateral infiltrates mildly increased on the right. Laboratory results included WBC 12.6 x10E9/L, FDA-CBER-2022-1614-4434424

RBC 3.60 x10E12/L, Hgb 10.9 gm/dL, Hct 34.0%, Cl 108 mmol/L, CO2 20 mmol/L, BUN 47 mg/dL, Cr 1.58 mg/dL, glucose 148 mg/dL, Ca 8.1 mg/dL, neutrophils 76.8%, lymphocytes 11.2%, and neutrophil absolute 9.67 x10E9/L.

On 07 Oct 2020, limited echocardiogram showed ejection fraction of 35-45%. Life vest was considered. Bronchoalveolar lavage Legionella culture was negative.

On 08 Oct 2020, vital signs included BP 168/86, pulse 92, respiratory rate 20, temperature 97.8 degrees Fahrenheit, and oxygen saturation 94%. Physical examination revealed coarse breath sounds, irregular rhythm, and minimal lower extremity edema. Treatment included amiodarone and apixaban for paroxysmal atrial fibrillation, prednisone for pneumonia, metoprolol and furosemide for hypertension, and clopidogrel was stopped. Acute kidney injury secondary to acute tubular necrosis and non-anion gap metabolic acidosis improved. Hypertension was increasing and hydralazine was resumed. Hypomagnesemia was repeated. The subject was discharged from the hospital in good condition with 2 liters of supplemental oxygen and Holter monitor for thirty days. Discharge diagnoses included community acquired pneumonia, elevated troponin, atrial fibrillation with rapid ventricular response, sepsis, and chest pain.

On 09 Oct 2020, cytomegalovirus polymerase chain reaction in bronchoalveolar lavage was not detected.

On 12 Oct 2020, the subject reported he was on 4 liters of supplemental oxygen and remained on prednisone.

On 15 Oct 2020, the subject was re-hospitalized for atrial fibrillation. He presented with atrial flutter/rapid ventricular response and symptoms of shortness of breath. Cardiology and pulmonary were consulted. Chest x-ray showed extensive bilateral infiltrates consistent with multifocal pneumonia slightly improved in the interval. Treatment included oral benzonatate for cough, intravenous diltiazem and intravenous amiodarone for paroxysmal atrial fibrillation, subcutaneous enoxaparin sodium for coronary artery disease.

On 16 Oct 2020, the subject was lying in bed, appeared comfortable. He continued intravenous amiodarone drip. He also continued 4 liters nasal cannula. Laboratory results included RBC 3.57, Hgb 10.6, HCT 32.9, sodium 133, Cr 1.51, glucose 222, Ca 8.0, albumin 2.7, total protein 4.8, and Hgb A1c 9.5. Treatment included subcutaneous insulin aspart for diabetes type II.

On 17 Oct 2020, the subject was discharged from the hospital. Discharge diagnoses included atrial fibrillation/rapid ventricular response, nonischemic cardiomyopathy, acute hypoxemic respiratory failure, diabetes, and acute kidney injury. As recommended by cardiology, apixaban was given upon discharge. Treatment included oral prednisone for pneumonia.

There was no action taken with study drug in response to the event of pneumonia, and paroxysmal atrial fibrillation.

Study drug was discontinued in response to the events of respiratory failure, non-ST elevated myocardial infarction, hypomagnesia, and acute kidney injury.

The event, cryptogenic organizing pneumonia, was reported as resolved with sequelae, the subject completed the antibiotic trials, but remained on home oxygen, which was being weaned, on 08 Oct 2020. The event, paroxysmal atrial fibrillation, was reported as resolved with sequelae, subject was in sinus rhythm but could intermittently go in and out of atrial fibrillation and on medication and following up with primary care physician to control and monitor, on 30 Oct 2020. The event, non-ST elevated myocardial infarction, was reported as resolved on 26 Sep 2020. The events, hypomagnesia and acute kidney injury, were reported as resolved on 08 Oct 2020. The event, respiratory failure, was reported as resolved on 17 Oct 2020.

The investigator assessed the events, cryptogenic organizing pneumonia, respiratory failure, paroxysmal atrial fibrillation, non-ST elevated myocardial infarction, hypomagnesia, and acute kidney injury, as related to study drug and not related to study procedure.

Follow up received on 06 Oct 2020 and 08 Oct 2020 included updated relationship to study drug to related for cough, pneumonia and respiratory failure (previously not related). In addition, treatment clarification was provided, and concomitant medication and course of illness was updated.

Follow up received on 12 Oct 2020, 13 Oct 2020, 15 Oct 2020, and 19 Oct 2020 included a discharge summary and medical records which provided additional medical history, course of illness, laboratory and diagnostic tests, and discharge diagnoses. The events of paroxysmal atrial fibrillation, non-ST elevated myocardial infarction, hypomagnesia, fever, and acute kidney injury were added. Medical history and concomitant medications were updated. Action taken with study drug was updated for respiratory failure. Start date was updated for pneumonia. Site confirmed the events of pneumonia and respiratory failure were ongoing on 20 Oct 2020.

Follow-up received on 21 Oct 2020 included updated concomitant medications, treatment, event details for pneumonia and

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respiratory failure, and diagnostic test results; discharge summary which provided additional course of illness, discharge diagnoses, and laboratory results.

Follow-up received on 28 Oct 2020, 30 Oct 2020, 02 Nov 2020, 03 Nov 2020 included updated medical history, removed events cough and fever, updated event term to cryptogenic organizing pneumonia (previously pneumonia), updated event outcomes of respiratory failure, paroxysmal atrial fibrillation, pneumonia.

Follow-up received on 09 Nov 2020 included no new information.

Case Comment/Sender's Comment:

Company Comment: This case concerns a 70-year-old, White, male subject with medical history of coronary artery disease with myocardial infarction and stent placement, pulmonary embolism, hypertension, hyperlipidemia and type 2 diabetes, who experienced the unexpected events of cryptogenic organizing pneumonia, respiratory failure, paroxysmal atrial fibrillation, non-ST elevated myocardial infarction, hypomagnesia, and acute kidney injury. The events cryptogenic organizing pneumonia, paroxysmal atrial fibrillation, non-ST elevated myocardial infarction, hypomagnesia, and acute kidney injury occurred 29 days after the first, and only, study vaccine administration. The event respiratory failure occurred 32 days after the first, and only, study vaccine administration. The events were considered unrelated to the study vaccine, noting that the events are more likely explained by the subject's comorbid conditions.

B6. LABORATORY DATA

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	09/27/2020	Blood albumin	3.1 g/dL	4.6 3.2
2	10/16/2020	Blood albumin	2.7 g/dL	4.6 3.2
3	09/30/2020	Blood calcium	8.1 mg/dl	10.4 8.4
4	10/06/2020	Blood calcium	8.1 mg/dl	10.4 8.4
5	10/16/2020	Blood calcium	8.0 mg/dl	10.4 8.4
6	09/29/2020	Blood chloride	110 millimole per litre	107 98
7	09/30/2020	Blood chloride	111 millimole per litre	107 98
8	10/06/2020	Blood chloride	108 millimole per litre	107 98
9	09/26/2020	Blood creatinine	2.59 mg/dl	1.25 0.72
10	09/27/2020	Blood creatinine	2.40 mg/dl	1.25 0.72
11	09/29/2020	Blood creatinine	2.25 mg/dl	1.25 0.72
12	09/30/2020	Blood creatinine	1.98 mg/dl	1.25 0.72
13	10/06/2020	Blood creatinine	1.58 mg/dl	1.25 0.72
14	10/16/2020	Blood creatinine	1.51 mg/dl	1.25 0.72
15	09/26/2020	Blood culture	1/2 with Staph hominis, likely contaminant. 2/2 no growth	
16	09/27/2020	Blood culture		

1/2 Revealed growth of gram positive cocci in clusters.
2/2 Showed no growth in 24 hours.

17	10/01/2020	Blood culture		
		Showed no growth.		
18	10/02/2020	Blood culture		
		Showed growth of Staphylococcus hominis		
		Possible contaminant unless multiple cultures were positive for the same isolate.		
19	09/26/2020	Blood glucose	466 mg/dl	105 70
20	09/27/2020	Blood glucose	120 mg/dl	105 70
21	09/29/2020	Blood glucose	160 mg/dl	105 70
22	09/30/2020	Blood glucose	116 mg/dl	105 70
23	10/06/2020	Blood glucose	148 mg/dl	105 70
24	10/16/2020	Blood glucose	222 mg/dl	105 70
25	09/26/2020	Blood magnesium	1.0 mg/dl	2.6 1.6
26	09/27/2020	Blood pressure measurement	142/61 mmHg	
27	09/29/2020	Blood pressure measurement	171/95 mmHg	
28	10/03/2020	Blood pressure measurement	159/90 mmHg	
29	10/08/2020	Blood pressure measurement	168/86 mmHg	
30	09/26/2020	Blood sodium	135 millimole per litre	145 138
31	10/16/2020	Blood sodium	133 millimole per litre	145 138
32	09/26/2020	Blood urea	47 mg/dl	25.7 8.4
33	09/27/2020	Blood urea	48 mg/dl	25.7 8.4
34	09/29/2020	Blood urea	63 mg/dl	25.7 8.4
35	09/30/2020	Blood urea	56 mg/dl	25.7 8.4
36	10/06/2020	Blood urea	47 mg/dl	25.7 8.4
37	09/26/2020	Body temperature	101 °F	
38	09/27/2020	Body temperature	98.1 °F	
39	09/28/2020	Body temperature	101 °F	

40	09/29/2020	Body temperature	97.4 °F	
41	10/03/2020	Body temperature	97.2 °F	
42	10/08/2020	Body temperature	97.8 °F	
43	09/30/2020	Bronchoalveolar lavage		
		No organisms seen and moderate Polymorphonuclear cells		
44	09/30/2020	Bronchoalveolar lavage	percent	
		Neutro 45%		
		Lymphocytes 73%		
		macrophage 32%		
		cells counted 100%		
45	10/01/2020	Bronchoalveolar lavage		
		Showed no growth, moderate Polymorphonuclear cells, and no organisms seen.		
46	10/02/2020	Bronchoalveolar lavage		
		Showed no growth, moderate Polymorphonuclear cells, and no organisms seen.		
47	09/30/2020	Bronchoscopy		
		Showed unresolved bilateral infiltrates, washings were obtained from endobronchial tree, bronchoalveolar lavage was performed from right upper lobe and right middle lobe, no evidence of diffuse alveolar hemorrhage, was negative for COVID, and culture results were pending.		
48	09/28/2020	C-reactive protein	31.37 mg/dl	<=0.50
49	09/26/2020	Carbon dioxide	18 millimole per litre	31 23
50	09/27/2020	Carbon dioxide	20 millimole per litre	31 23
51	09/29/2020	Carbon dioxide	17 millimole per litre	31 23
52	09/30/2020	Carbon dioxide	20 millimole per litre	31 23
53	10/06/2020	Carbon dioxide	20 millimole per litre	31 23
54	09/26/2020	Chest X-ray		
		Showed bilateral infiltrates consistent with multifocal pneumonia which was a pattern consistent with but not diagnostic for COVID-19 pneumonia.		
55	09/28/2020	Chest X-ray		
		Showed increasing bilateral patchy airspace consolidation, right greater than left.		
56	10/06/2020	Chest X-ray		
		Showed bilateral infiltrates mildly increased on the right		
57	10/15/2020	Chest X-ray		

Shown extensive bilateral infiltrates consistent with multifocal pneumonia slightly improved in the interval.

58	09/29/2020	Computerised tomogram thorax		
		Findings in keeping with multifocal pneumonia, no lobe was spared; a follow-up chest CT was recommended after the appropriate course of therapy to document resolution of these findings; small bilateral pleural effusions, right greater than left; esophageal wall thickening, nonspecific to be correlated for esophageal reflux.		
59	09/26/2020	Culture urine	<10,000 CFU/ml	
		Urogenital flora		
60	10/02/2020	Cytology		
		Lungs, right and left, bronchial washing cytology: No cytological diagnosis and negative for malignancy		
61	10/09/2020	Cytomegalovirus test		
		Not detected		
62	09/28/2020	Echocardiogram		
		Shown cardiomyopathy with ejection fraction 30-35%.		
63	09/29/2020	Echocardiogram		
		Shown left ventricle was normal in size, moderately to markedly reduced systolic left ventricular function, ejection fraction 30-35%, left ventricle wall thickness was normal, no regional wall motion abnormalities, left ventricular diastolic function parameters were normal, and right ventricular systolic pressure was 30 mmHg.		
64	10/07/2020	Echocardiogram		
		Limited		
		Shown ejection fraction of 35-45%.		
65	10/05/2020	Fungal test		
		Shown no fungus isolated, no yeast or hyphae seen, and no Pneumocystis jiroveciumocys.		
66	09/27/2020	Glycosylated haemoglobin	9.0 percent	5.6 4.2
67	10/16/2020	Glycosylated haemoglobin	9.5 percent	5.6 4.2
68	09/30/2020	Gram stain		
		From bronchoalveolar lavage showed moderate polymorphonuclear cells and no organisms seen.		
69	09/26/2020	Haematocrit	33.5 percent	51.7 35.2
70	09/27/2020	Haematocrit	33.8 percent	51.7 35.2
71	09/29/2020	Haematocrit	34.6 percent	51.7 35.2
72	09/30/2020	Haematocrit	30.9 percent	51.7

				35.2
73	10/06/2020	Haematocrit	34.0 percent	51.7
				35.2
74	10/16/2020	Haematocrit	32.9 percent	51.7
				35.2
75	09/26/2020	Haemoglobin	11.3 g/dL	17.6
				12.0
76	09/27/2020	Haemoglobin	11.0 g/dL	17.6
				12.0
77	09/29/2020	Haemoglobin	11.2 g/dL	17.6
				12.0
78	09/30/2020	Haemoglobin	10.1 g/dL	17.6
				12.0
79	10/06/2020	Haemoglobin	10.9 g/dL	17.6
				12.0
80	10/16/2020	Haemoglobin	10.6 g/dL	17.6
				12.0
81	09/27/2020	Heart rate	96 heart beats per minute	
82	09/29/2020	Heart rate	72 heart beats per minute	
83	10/03/2020	Heart rate	97 heart beats per minute	
84	10/08/2020	Heart rate	92 heart beats per minute	
85	10/04/2020	Herpes simplex test Negative		
86	09/29/2020	Legionella test Negative		
87	10/07/2020	Legionella test Negative		
88	09/26/2020	Lymphocyte count	0.24 10 ⁹ /L	3.94
				1.07
89	09/27/2020	Lymphocyte count	0.38 10 ⁹ /L	3.94
				1.07
90	09/29/2020	Lymphocyte count	0.02 10 ⁹ /L	3.94
				1.07
91	09/26/2020	Lymphocyte percentage	2.2 percent	43.0
				20.0
92	09/27/2020	Lymphocyte percentage	2.7 percent	43.0
				20.0
93	09/29/2020	Lymphocyte percentage	1.5 percent	43.0
				20.0
94	10/06/2020	Lymphocyte percentage	11.2 percent	43.0
				20.0
95	09/29/2020	Monocyte percentage	2.4 percent	1
				0
96	10/05/2020	Mycobacterium test Showed no acid-fast bacilli.		
97	09/26/2020	Neutrophil count	9.75 10 ⁹ /L	7.14
				2.01
98	09/27/2020	Neutrophil count	13.21 10 ⁹ /L	7.14
				2.01

99	09/29/2020	Neutrophil count	19.80 10 ⁹ /L	7.14 2.01
100	10/06/2020	Neutrophil count	9.67 10 ⁹ /L	7.14 2.01
101	09/26/2020	Neutrophil percentage	90.5 percent	73.0 44.0
102	09/27/2020	Neutrophil percentage	91.0 percent	73.0 44.0
103	09/29/2020	Neutrophil percentage	94.6 percent	73.0 44.0
104	10/06/2020	Neutrophil percentage	76.8 percent	73.0 44.0
105	09/27/2020	Oxygen saturation improved to 93	76 percent	
106	09/29/2020	Oxygen saturation	97 percent	
107	10/03/2020	Oxygen saturation	95 percent	
108	10/08/2020	Oxygen saturation	94 percent	
109	10/01/2020	Pathology test Revealed no malignancy		
110	09/26/2020	Procalcitonin	2.76 ng/mL	<0.10
111	09/27/2020	Protein total	6.2 g/dL	8.3 6.4
112	10/16/2020	Protein total	4.8 g/dL	8.3 6.4
113	09/26/2020	Red blood cell count	3.72 10 ¹² /L	5.40 3.80
114	09/27/2020	Red blood cell count	3.63 10 ¹² /L	5.40 3.80
115	09/29/2020	Red blood cell count	3.69 10 ¹² /L	5.40 3.80
116	10/06/2020	Red blood cell count	3.60 10 ¹² /L	5.40 3.80
117	10/16/2020	Red blood cell count	3.57 10 ¹² /L	5.40 3.80
118	09/27/2020	Respiratory rate	25 breaths per minute	
119	09/29/2020	Respiratory rate	24 breaths per minute	
120	10/03/2020	Respiratory rate	20 breaths per minute	
121	10/08/2020	Respiratory rate	20 breaths per minute	
122	09/26/2020	Respiratory viral panel Negative		
123	09/30/2020	Respiratory viral panel Negative		FDA-CBER-2022-1614-4434431

124	09/27/2020	SARS-CoV-2 test Negative Nasopharyngeal		
125	09/28/2020	SARS-CoV-2 test Negative Nasopharyngeal		
126	09/28/2020	Serum ferritin	334 ng/mL	276 22
127	09/29/2020	Streptococcus test Negative		
128	09/26/2020	Troponin	2.415 ng/mL	<0.038
		Elevated on admission, likely secondary to demand ischemia from rapid atrial fibrillation.		
129	09/27/2020	Troponin	1.643 ng/mL	<0.038
130	09/26/2020	Urine analysis		
		Color yellow, protein 3+, blood 1+, leukocyte trace, glucose 3+, and WBC greater than 100.		
131	09/26/2020	White blood cell count	10.8 10 ⁹ /L	10.7 4.4
132	09/27/2020	White blood cell count	14.5 10 ⁹ /L	10.7 4.4
133	09/29/2020	White blood cell count	20.0 10 ⁹ /L	10.7 4.4
134	09/30/2020	White blood cell count	15.9 10 ⁹ /L	10.7 4.4
135	10/06/2020	White blood cell count	12.6 10 ⁹ /L	10.7 4.4

B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1	--/--/1951 Ongoing	Current Condition Seasonal allergy	
2	--/--/1951 Ongoing	Historical Condition SEASONAL ALLERGIES	
3	--/--/1975 --/--/1975	Historical Condition Joint dislocation	Right
4	--/--/1975 --/--/1975	Historical Condition RIGHT SHOULDER DISLOCATION	
5	--/--/1992 Ongoing	Current Condition Type 2 diabetes mellitus	

6	--/--/1992 Ongoing	Historical Condition Hypertension	
7	--/--/1992 Ongoing	Historical Condition TYPE 2 DIABETES	
8	--/--/1999 UNK	Procedure Cataract operation	Per discharge summary
9	--/--/2004 UNK	Procedure Coronary arterial stent insertion	Per discharge summary; x3 diagonal branch
10	06/13/2008 Ongoing	Historical Condition Depression	
11	06/13/2008 UNK	Historical Condition Coronary artery disease	Per discharge summary; CAD
12	06/13/2008 UNK	Historical Condition Depression	Per discharge summary; not elsewhere classified
13	06/13/2008 UNK	Historical Condition Hyperlipidaemia	Per discharge summary
14	06/13/2008 UNK	Historical Condition Obesity	Per discharge summary
15	04/10/2009 UNK	Procedure Colonoscopy	Per discharge summary; negative exam, mild diverticulosis
16	11/13/2009 UNK	Historical Condition Erectile dysfunction	Per discharge summary; of organic origin
17	--/--/2010 Ongoing	Historical Condition Insomnia	
18	01/15/2011 UNK	Historical Condition Diabetes mellitus	Per discharge summary; with renal complications
19	05/05/2011 UNK	Procedure Catheterisation cardiac	Per discharge summary; balloon angioplasty of distal RCA
20	05/12/2011 UNK	Procedure Coronary arterial stent insertion	Per discharge summary; drug-eluting stents right coronary artery
21	10/10/2011 10/31/2011	Historical Condition Gastritis	
22	10/10/2011 UNK	Procedure Oesophagogastroduodenosc opy	Per discharge summary

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23	10/12/2011 10/31/2011	Historical Condition Helicobacter infection	
24	10/12/2011 10/31/2011	Historical Condition H. PYLORI INFECTION	
25	01/24/2012 Ongoing	Historical Condition Chronic kidney disease	
26	--/--/2013 --/--/2013	Historical Condition Coronary artery disease	
27	09/30/2013 UNK	Procedure Intervertebral disc operation	Per discharge summary; left, micro
28	01/08/2014 UNK	Historical Condition Cellulitis	Right lower extremity
29	01/08/2014 01/18/2014	Historical Condition Pyuria	
30	01/08/2014 01/18/2014	Historical Condition Pulmonary embolism	
31	01/08/2014 UNK	Historical Condition International normalised ratio	Per discharge summary; prolonged
32	01/08/2014 UNK	Historical Condition Septic pulmonary embolism	Per discharge summary
33	01/08/2014 UNK	Historical Condition RIGHT LOWER EXTREMITY CELLULITIS	
34	01/09/2014 UNK	Procedure Echocardiogram	Per discharge summary; no evidence vegetation
35	01/11/2014 04/--/2016	Historical Condition Staphylococcus test positive	Per discharge summary
36	01/13/2014 Ongoing	Historical Condition Iron deficiency anaemia	
37	07/21/2014 Ongoing	Current Condition Diabetic neuropathy	Sensory
38	07/21/2014 Ongoing	Historical Condition SENSORY DIABETIC NEUROPATHY	
39	01/06/2015 UNK	Procedure Incision site abscess	Per discharge summary; drainage, left hip

40	--/--/2015 Ongoing	Historical Condition Back pain	Low
41	--/--/2015 Ongoing	Historical Condition Hyperlipidaemia	
42	04/28/2016 Ongoing	Current Condition Mitral valve incompetence	
43	04/28/2016 UNK	Historical Condition Coronary arterial stent insertion	Per discharge summary; artery, x2 to R1
44	04/28/2016 UNK	Procedure Catheterisation cardiac	Per discharge summary; 2.25x12 and 2.25x12 resolute DES to R1 x2
45	04/28/2016 Ongoing	Historical Condition MITRAL VALVE REGURGITATION	
46	05/19/2016 UNK	Procedure Catheterisation cardiac	Per discharge summary
47	03/31/2017 UNK	Procedure Lesion excision	Per discharge summary; of posterior scalp abscess
48	--/--/2017 --/--/2017	Historical Condition Staphylococcus test positive	Positive
49	--/--/2017 --/--/2017	Historical Condition MRSA POSITIVE	
50	11/02/2017 UNK	Procedure Catheterisation cardiac	Per discharge summary
51	11/09/2017 UNK	Procedure Echocardiogram	Per discharge summary; shoulder procedure
52	04/20/2018 04/20/2018	Procedure Coronary arterial stent insertion	
53	04/20/2018 04/20/2018	Historical Condition CORONARY ARTERY STENT	
54	06/13/2019 UNK	Procedure Polypectomy	Per discharge summary; colonoscopy with
55	--/--/2019 Ongoing	Current Condition Corneal erosion	Left lens

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56	--/--/2019 Ongoing	Current Condition Diabetic retinopathy	Left eye
57	--/--/2019 Ongoing	Historical Condition LEFT LENS EROSION	
58	--/--/2019 Ongoing	Historical Condition DIABETIC RETINOPATHY LEFT EYE	
59	06/17/2019 06/30/2019	Historical Condition Diverticulum intestinal	
60	06/17/2019 06/17/2019	Historical Condition Colon adenoma	
61	06/17/2019 06/17/2019	Procedure Colonoscopy	
62	06/17/2019 06/30/2019	Historical Condition DIVERTICULOSIS OF COLON	
63	06/17/2019 06/17/2019	Historical Condition ADENOMATOUS COLON POLYP	
64	06/17/2019 06/17/2019	Historical Condition COLONOSCOPY	
65	11/01/2019 11/01/2019	Historical Condition Myocardial infarction	
66	11/01/2019 UNK	Historical Condition Acute myocardial infarction	Per discharge summary
67	11/05/2019 UNK	Procedure Catheterisation cardiac	Per discharge summary; patent ramus stent, occluded/small caliber diagonal stent
68	11/--/2019 Ongoing	Historical Condition Urinary retention	
69	11/--/2019 Ongoing	Historical Condition Benign prostatic hyperplasia	
70	12/18/2019 UNK	Historical Condition Benign prostatic hyperplasia	Per discharge summary; with urinary retention
71	--/--/2020 Ongoing	Current Condition Wound	Right elbow

72	--/--/2020 Ongoing	Historical Condition WOUND RIGHT ELBOW	
73		Historical Condition Exposure to communicable disease	
74	Ongoing	Current Condition Urinary tract infection	
75		Historical Drug Drug hypersensitivity; Drug Indication: Cough	Per discharge summary Ace inhibitor
76		Historical Condition Exposure to lead	Per discharge summary; personal history of contact with and (suspected)
77		Procedure Appendectomy	Per discharge summary
78		Procedure Arthrotomy	Per discharge summary; right shoulder, x2
79		Procedure Cataract operation	Per discharge summary; removal left; 08 NOV
80		Procedure Surgery	Per discharge summary; shoulder procedure
81		Historical Condition Neoplasm malignant	
82		Historical Condition Parkinson's disease	
83		Historical Condition Cardiac failure	
84		Historical Condition Cardiac disorder	
85	Ongoing	Historical Condition RECURRENT URINARY TRACT INFECTIONS	

C4. DIAGNOSIS FOR USE (Continued)

#1:COVID-19 vaccination (COVID-19 immunisation)

C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

to ongoing

2) LANTUS (INSULIN GLARGINE) --/--/2018 to ongoing

3) TRAZODONE (TRAZODONE) --/--/2010 to ongoing

- 4) VICTOZA (LIRAGLUTIDE) --/--/2017 to ongoing
- 5) PLAVIX (CLOPIDOGREL BISULFATE) --/--/2013 to 10/08/2020
- 6) HYDRALAZINE (HYDRALAZINE) 02/--/2020 to ongoing
- 7) TAMULOSIN (TAMSULOSIN HYDROCHLORIDE) 02/--/2020 to ongoing
- 8) FINASTERIDE (FINASTERIDE) 11/--/2019 to ongoing
- 9) AMLODIPINE (AMLODIPINE) --/--/2013 to 10/15/2020
- 10) METFORMIN (METFORMIN) --/--/2015 to 10/08/2020
- 11) ATORVASTATIN (ATORVASTATIN) --/--/2015 to ongoing
- 12) ASPIRIN --/--/2013 to UNK
- 13) ASPIRIN 09/26/2020 to 09/26/2020
- 14) ASPIRIN 09/27/2020 to 10/08/2020
- 15) TRAZADONE --/--/2010 to UNK
- 16) CORICIDIN [DEXTROMETHORPHAN/CHLOROPHENIRAMINE MALEATE] 09/22/2020 to 09/26/2020
- 17) AMIODARONE (AMIODARONE) 10/06/2020 to UNK
- 18) AMIODARONE (AMIODARONE) 10/05/2020 to 10/05/2020
- 19) AMIODARONE (AMIODARONE) 10/05/2020 to 10/06/2020
- 20) AMIODARONE (AMIODARONE) 10/15/2020 to 10/15/2020
- 21) APIXABAN (APIXABAN) 10/08/2020 to UNK
- 22) PREDNISONE (PREDNISONE) 10/02/2020 to 10/15/2020
- 23) PREDNISONE (PREDNISONE) 10/17/2020 to 10/24/2020
- 24) PREDNISONE (PREDNISONE) 10/25/2020 to 11/01/2020
- 25) METOPROLOL XL (METOPROLOL TARTRATE) 10/08/2020 to UNK
- 26) EFFEXOR XR 10/08/2020 to UNK
- 27) ROCEPHIN 09/26/2020 to 09/28/2020
- 28) AZITHROMYCIN (AZITHROMYCIN) 09/26/2020 to 09/28/2020
- 29) MAGNESIUM (MAGNESIUM) 09/26/2020 to 09/26/2020
- 30) NORCO [HYDROCODONE/ACETAMINOPHEN] 09/29/2020 to 10/01/2020
- 31) ONDANSETRON (ONDANSETRON) 09/27/2020 to 09/27/2020
- 32) LOVENOX 09/26/2020 to 09/28/2020
- 33) LOVENOX 10/01/2020 to 10/02/2020
- 34) LOVENOX 10/15/2020 to 10/17/2020
- 35) TESSALON (BENZONATATE) 09/27/2020 to 09/29/2020
- 36) TESSALON (BENZONATATE) 10/15/2020 to UNK
- 37) NOVOLOG (INSULIN ASPART) 09/26/2020 to 10/08/2020
- 38) NOVOLOG (INSULIN ASPART) 10/16/2020 to 10/17/2020
- 39) DECADRON 09/26/2020 to 09/27/2020
- 40) LEVAQUIN (LEVOFLOXACIN) 09/28/2020 to 09/28/2020
- 41) MUCINEX DM [DEXTROMETHORPHAN/GUAIFENESIN] 09/29/2020 to 10/08/2020
- 42) ALBUTEROL 0.5% 09/30/2020 to 09/30/2020
- 43) LIDOCAINE 4% 09/30/2020 to 09/30/2020
- 44) LEVALBUTEROL 09/30/2020 to 10/02/2020
- 45) DILTIAZEM (DILTIAZEM) 10/01/2020 to 10/01/2020
- 46) DILTIAZEM (DILTIAZEM) 10/15/2020 to 10/15/2020
- 47) DIGOXIN (DIGOXIN) 10/05/2020 to 10/05/2020
- 48) LASIX 10/08/2020 to 10/08/2020

G8. ADVERSE EVENT TERMS (Continued)

failure, Non ST segment elevation myocardial infarction, Hypomagnesemia, Acute kidney injury