

Subject ID	MCN
US3142100	(b) (6)
Preferred Term:	COVID-19
Treatment Assignment:	Placebo
Baseline SARS-CoV-2	Negative

This 69-year-old, white, male subject experienced a non-serious adverse event of COVID-19. The subject's medical history did not include any health risk factors for severe COVID 19. The subject received his first dose on 04 Aug 2020 and 2nd dose on 03 Sep 2020.

On 21 Sep 2020, the subject began having mild symptoms late in the day after his spouse had received a positive COVID-19 test from another facility. On 23 Sep 2020, the subject was seen onsite for COVID-19 confirmation testing. A nasopharyngeal rapid polymerase chain reaction for SARS-CoV-2 was positive. The subject experienced mild cough, mild shortness of breath, mild difficulty breathing, mild muscle aches (myalgia), mild body aches, mild headache, and mild nasal congestion. The subject's oxygen saturation was 93%, temperature was 98.9 degrees Fahrenheit, pulse 86 beats per minute, respiratory rate 14 breaths per minute, and blood pressure 115/88 mmHg. On 24 Sep 2020, the subject experienced mild fatigue.

On 25 Sep 2020, the subject experienced the new symptom of mild body aches.

On 27 Sep 2020, the subject started oral ibuprofen for fever. On 28 Sep 2020, the subject experienced the new symptom of runny nose. **The subject's oxygen saturation was 90% from 01-05 Oct 2020.** On 05 Oct 2020, treatment included oral acetaminophen for fever of 101 degrees Fahrenheit. The subject did not visit any other medical facility outside of the research site while experiencing COVID-19. On 14 Oct 2020, his oxygen saturation was 93%. On 20 Oct 2020, his body temperature was 97.6 degrees Fahrenheit, pulse 77 beats per minute, respiratory rate 10 breaths per minute, and blood pressure 124/83 mmHg. Action taken with study drug was not applicable as the subject had already received both scheduled doses. At the time of this report, the event had not yet resolved.

Subject ID	MCN
US3262099	(b) (6)
Preferred Term:	COVID-19
Treatment Assignment:	Placebo
Baseline SARS-CoV-2	Negative

This 61-year-old, white male subject experienced a non-serious adverse event of COVID-19. The subject's medical history was significant for cardiac disease and severe obesity. The subject received his first dose on 05 Aug 2020 and 2nd dose on 03 Sep 2020.

On 12 Oct 2020, the subject began to experience moderate cough, fatigue, muscle aches and body aches. A nasopharyngeal rapid polymerase chain reaction for SARS-CoV-2 performed was positive. **The subject's oxygen saturation was 93% on the 15th and 23rd of Oct 2020.** On 24 Oct 2020, the subject's symptoms were mild in severity and his oxygen saturation was improving between 94-97 over the course of the following two week. Action taken with study drug was not applicable as the subject had already received both scheduled doses. At the time of this report, the event had not yet resolved.

Subject ID	MCN
US3272195	(b) (6)
Preferred Term:	COVID-19, Pneumonia, Hypoxia
Treatment Assignment:	Placebo
Baseline SARS-CoV-2	Negative

This 44-year-old, Hispanic or Latino, white, female experienced a serious event of COVID 19, pneumonia secondary to COVID 19 positive infection, and hypoxia. The subject's medical history did not include any health risk factors for severe COVID 19. The subject received her first dose on 19 Aug 2020 and 2nd dose on 17 Sep 2020.

The subject was exposed to COVID-19 from a coworker and a nasopharyngeal rapid polymerase chain reaction for SARS-CoV-2 performed was positive. She was treated with oral (PO) guaifenesin and PO sambucus nigra/ zinc, oral colecalciferol and oral ascorbic acid. From 30 Oct 2020 through 22 Nov 2020, the subject intermittently experienced mild to severe chills, cough, shortness of breath, difficulty breathing, fatigue, muscle aches, body aches, headache, loss of taste, loss of smell, nasal congestion, runny nose, nausea, and diarrhea. She denied vomiting or sore throat. On 02 Nov 2020, treatment included PO paracetamol and PO melatonin. From 03 Nov 2020 through 06 Nov 2020, temperature was 100.4 F to 101.2 degrees Fahrenheit (F) and **the subject's oxygen saturation intermittently ranged from 85%-92% on 05 Nov 2020 through 15 Nov 2020.** On 07 Nov 2020 she was hospitalized due to worsening COVID-19, pneumonia secondary to COVID-19 positive infection and hypoxia. Radiographical evidence confirmed COVID-19. Temperature returned to normal, 98.7 F. She received supplemental oxygen, intravenous (IV) antibiotics including azithromycin and ceftriaxone, PO dexamethasone, IV remdesivir, and IV convalescent plasma. On 12 Nov 2020, the subject was discharged from the hospital. Treatment included PO azithromycin and IV potassium. On 16 Nov 2020, the subject's oxygen saturation returned to normal, 98%. From 23 Nov through 28 Nov 2020, the subject intermittently experienced mild cough, shortness of breath, and nasal congestion. The event, hypoxia, resolved on 12 Nov 2020 and pneumonia on 30 Nov 2020. The subject presented for a convalescent visit on 30 Nov 2020. At that time lungs clear to auscultation, breathing without effort, no supplemental O2, no respiratory, pneumonia, or Covid medications, and no respiratory symptoms. Action taken with study drug was not applicable as the subject had already received both scheduled doses. At the time of this report, the event had not yet resolved.

Subject ID	MCN
US3312605	(b) (6)
Preferred Term:	COVID-19
Treatment Assignment:	Placebo
Baseline SARS-CoV-2	Negative

This 24-year-old, white, male subject experienced a serious adverse event of symptomatic COVID-19. The subject's medical history did not include any health risk factors for severe COVID 19. The subject received his first dose on 10 Sep 2020 and 2nd dose on 08 Oct 2020.

From 19 Oct 2020 through 4 Nov 2020 subject intermittently experienced moderate cough, severe fatigue, severe body and muscle aches, severe nausea, severe vomiting, severe diarrhea, severe sore throat, moderate chills, severe shortness of breath, severe difficulty breathing, severe nasal congestion, as well as severe loss of taste and smell. Subject denied any rhinorrhea. A nasopharyngeal rapid polymerase chain reaction for SARS-CoV-2 performed was positive. Subject's treatment included oral acetaminophen/dextromethorphan/phenylephrine, oral acetaminophen/doxylamine/dextromethorphan, oral acetaminophen, and oral ibuprofen. Further treatment included oral zinc, oral melatonin, oral famotidine, oral ascorbic acid and albuterol inhaler. **On 27 Oct 2020, due to worsening of symptoms, subject was admitted to the hospital with an oxygen saturation of 85%.** Treatment included benzonatate, albuterol sulfate nebulizer, and intravenous hydration. Post treatment, oxygen saturation was considered much improved without the use of supplemental oxygen. The site reports that the subject had no known exposure or risk factors for COVID-19. On 29 Oct 2020, the subject was discharged from the hospital. On 02 Nov 2020, he reported steady improvement since discharge, with resolution of symptoms. On 04 Nov 2020, at site visit, the subject's physical examination was normal and oxygen saturation was 98%. Action taken with study drug was not applicable as the subject had already received both scheduled doses.

On November 13th, the subject notified the site that he wished to no longer participate in the study and gave no reason. The Investigator has since reported that they are unable to confirm the subject's account of COVID-19 illness, as the hospital at which he reported being admitted has no record of admission. Also, the subject did not produce a copy of his initial SARS-CoV-2 test. The Investigator has raised concerns about the accuracy of the subject's reporting. Moderna is working with the Investigator to determine what information in the participant's case report form can be considered reliable and will take further action based on this assessment.

Subject ID	MCN
US3332001	(b) (6)
Preferred Term:	COVID-19
Treatment Assignment:	Placebo
Baseline SARS-CoV-2	Negative

This 68-year-old, white, male subject experienced the non-serious event of COVID-19. The subject's medical history was significant for hypertension. The subject received his first dose on 03 Aug 2020 and 2nd dose on 28 Aug 2020.

On 30 Sep 2020, the subject experienced COVID-19 with a positive SARS-CoV-2 real-time reverse transcription polymerase chain reaction nasopharyngeal swab. Risk factor included his nephew was suspected of exposure. Vital signs included temperature 98.7 degrees Fahrenheit, pulse 98 beats/min, respiratory rate 16 breaths/min, and **blood pressure 88/61 mmHg**. He took no medications and had no interventions. On 01 Oct 2020, the subject experienced symptoms of mild muscle aches with vital signs of oxygen saturation 96% and temperature 97.6 degrees Fahrenheit the following day. The event, COVID-19, was considered resolved on 02 Oct 2020. Action taken with study drug was not applicable as the subject had already received both scheduled doses.

Subject ID	MCN
US3382152	(b) (6)
Preferred Term:	COVID-19
Treatment Assignment:	Placebo
Baseline SARS-CoV-2	Negative

This 29-year-old, white, female subject experienced the non-serious event of COVID-19. The subject's medical history did not include any health risk factors for severe COVID 19. The subject received her first dose on 31 Aug 2020 and 2nd dose on 02 Oct 2020

On 28 Oct 2020, the subject experienced COVID-19. Symptoms included mild cough, mild nasal congestion and mild runny nose. Treatment included oral cetirizine. On 29 Oct 2020, the subject experienced the new symptoms of moderate shortness of breath and moderate difficulty breathing, mild fatigue and mild new loss of smell. Vital signs included temperature 99.0 degrees Fahrenheit (F). Treatment included oral paracetamol and ibuprofen and albuterol inhalant. From 29 Oct through 10 Nov 2020, the subject intermittently experienced mild to moderate cough, shortness of breath, difficulty breathing, fatigue, new loss of smell, nasal congestion and runny nose. They denied experiencing chills, muscle aches, body aches, headache, new loss of taste, nausea, vomiting diarrhea or sore throat. On 02 Nov 2020, the subject had a positive SARS-CoV-2 real-time reverse transcription polymerase chain reaction nasopharyngeal swab. The subject's vital signs included oxygen (O2) saturation 95%, temperature 96.0 F, pulse 63 beats/min, respiratory rate 15 breaths/min and blood pressure 114/89. **On 03 Nov 2020 and 04 Nov 2020, the subject had an O2 saturation of 91%.** On 07 Nov 2020, nasal congestion resolved and cough, shortness of breath, difficulty breathing, fatigue and new loss of smell resolved on 09 Nov 2020 with complete recovery on 11 Nov 2020. Action taken with study drug was not applicable as the subject had already received both scheduled doses.

Subject ID	MCN
US3402029	(b) (6)
Preferred Term:	COVID-19
Treatment Assignment:	Placebo
Baseline SARS-CoV-2	Negative

This 34-year-old, white, female subject and experienced an SAE of COVID-19. The subject's medical history was significant for obesity. The subject received her first dose on 27 Jul 2020 and 2nd dose on 24 Aug 2020

On 29 Sep 2020, the subject experienced COVID-19. The subject was exposed to COVID-19 at place of employment and became symptomatic. The site was notified by subject's friend that her oxygen saturation declined, and she had difficulty breathing. On 30 Sep 2020, the subject had a positive SARS-CoV-2 real-time reverse transcription polymerase chain reaction nasopharyngeal swab. The subject experienced mild chills, mild cough, mild fatigue, mild muscle aches, mild headache, mild loss of taste, mild nasal congestion, mild sore throat, nausea, vomiting, and poor appetite. Vital signs included oxygen saturation 98%, temperature 98.1 degrees Fahrenheit, pulse 102 beats/min, respiratory rate 16 breaths/min and blood pressure 121/92 mmHg.

On 01 Oct 2020, the subject experienced the new symptom of mild loss of smell. Vital signs included oxygen saturation 99% and temperature 100.5 degrees Fahrenheit. On 02 Oct 2020, vital signs included oxygen saturation 97% and temperature 101.0 degrees Fahrenheit.

On 03 Oct 2020, vital signs included oxygen saturation 94% and temperature 102.0 degrees Fahrenheit. Treatment for the event included oral guaifenesin. The subject was taking ibuprofen and paracetamol for fever. On 04 Oct 2020, the subject experienced the new symptom of mild diarrhea. Vital signs included oxygen saturation 94% and temperature 98.9 degrees Fahrenheit.

On 05 Oct 2020, treatment for the event included oral dexamethasone. On 06 Oct 2020, the subject felt better. On 07 Oct 2020, the subject went to the emergency room where she was later admitted to the COVID unit of the hospital. The subject was treated with apixaban and dexamethasone in outpatient setting. **Vital signs included oxygen saturation 88%** and temperature 101.0 degrees Fahrenheit. The subject experienced the new symptom of moderate shortness of breath. A chest x-ray showed bibasilar infiltrate. Treatment for the event included oxygen, oral doxycycline, oral remdesivir, and intravenous convalescent plasma. **On 08 Oct 2020, vital signs included oxygen saturation 83%** and temperature 101.4 degrees Fahrenheit. On 09 Oct 2020, vital signs included **oxygen saturation 88%** and temperature 98.2 degrees Fahrenheit. On 13 Oct 2020, the subject was examined on the bedside. She was hemodynamically stable. She had some dry cough without sputum production. On 13 Oct 2020, the subject was discharged from the hospital and events were considered resolved. Action taken with study drug was not applicable as the subject had already received both scheduled doses.

Subject ID	MCN
US3452332	(b) (6)
Preferred Term:	COVID-19
Treatment Assignment:	Placebo
Relationship	Not Related
Baseline SARS-CoV-2	Negative

This 65-year-old, white, male subject experienced the non-serious event of COVID 19. The subject's medical history was significant for cardiac disease and diabetes type II. The subject received his first dose on 07 Aug 2020 and 2nd dose on 03 Sep 2020.

The subject had an occupational risk (truck driver) of exposure for COVID-19.

On 26 Oct 2020, the subject experienced COVID 19 with a positive SARS-CoV-2 real-time reverse transcription polymerase chain reaction nasopharyngeal swab. From 26 Oct 2020 through 13 Nov 2020, the subject intermittently experienced mild to moderate chills, cough, shortness of breath, difficulty breathing, fatigue, muscle aches (myalgia), body aches, headache, loss of taste, loss of smell, nasal congestion, runny nose, nausea, diarrhea, and sore throat. From 30 Oct 2020 through 01 Nov 2020, temperature was 101.2-100.4 degrees Fahrenheit (F). On 31 Oct 2020, **oxygen saturation was 91%**. On 02 Nov 2020, temperature normalized, 99.3 F. On 03 Nov 2020, oxygen saturation was 93% and normalized to 97% the following day. Action taken with study drug was not applicable as the subject had already received both scheduled doses.

Subject ID	MCN
US3752162	(b) (6)
Preferred Term:	COVID-19
Treatment Assignment:	Placebo
Relationship	Not Related
Baseline SARS-CoV-2	Negative

This 70-year-old, white, male subject experienced the non-serious event of COVID-19 infection. The subject's medical history was significant for asthma. The subject received his first dose on 19 Aug 2020 and 2nd dose on 16 Sep 2020.

The subject had an occupational risk (healthcare worker) of exposure for COVID-19 and was exposed on 13 Oct 2020. On 17 Oct 2020, the subject experienced COVID-19 infection with a positive SARS-CoV-2 real-time reverse transcription polymerase chain reaction saliva test collected on 27 Oct 2020. Symptoms included moderate cough, moderate fatigue, moderate muscle aches, moderate body aches and moderate headache. Treatment included oral paracetamol. On 18 Oct 2020, new symptoms included moderate shortness of breath. Vital signs included temperature 100.6 degrees Fahrenheit and **oxygen saturation 88%**. On 19 Oct 2020, vital signs included temperature 98.3 degrees Fahrenheit and oxygen saturation 95% and was treated with oral famotidine and oral paracetamol/ diphenhydramine. On 21 Oct 2020, experienced mild runny nose and the following day severe loss of taste and loss of smell. Treatment included oral zinc acetate/ zinc gluconate. On 24 Oct 2020, new symptoms included mild chills and mild diarrhea. On 28 Oct 2020, treatment included oral colecalciferol and oral ascorbic acid. On 02 Nov 2020, symptoms had resolved. Action taken with study drug was not applicable as the subject had already received both scheduled doses.

Subject ID	MCN
US3752229	(b) (6)
Preferred Term:	COVID-19
Treatment Assignment:	Placebo
Relationship	Not Related
Baseline SARS-CoV-2	Negative

This 45-year-old, Latino, female subject experienced the non-serious event of symptomatic COVID-19. The subject's medical history was significant for hypertension and cardiac arrhythmias. The subject received her first dose on 24 Aug 2020 and 2nd dose on 21 Sep 2020.

On 23 Oct 2020, the subject experienced symptomatic COVID-19 with a positive SARS-CoV-2 real-time reverse transcription polymerase chain reaction nasopharyngeal swab collected on 27 Oct 2020. Between 23 Oct 2020 and 12 Nov 2020, the subject intermittently experienced mild to severe symptoms of chills, sore throat, headache, cough, fatigue, muscle aches, body aches, nausea, loss of taste and smell, nasal congestion, runny nose and vomiting. During this period the subject did not report any of the following symptoms including diarrhea, shortness of breath and difficult breathing. The subject's known exposure risks include working in a healthcare setting with frequent contact with COVID-19 positive patients. However, the subject is always in full personal protection equipment (PPE). The subject's spouse and two children were also COVID-19 positive. Treatment included ibuprofen, acetaminophen/ dextromethorphan HBr/doxylamine succinate, acetaminophen/dextromethorphan HBr/phenylephrine HCl, azithromycin and benzonatate. Between 28 Oct 2020 and 03 Nov 2020, the subject experienced fever ranging from 100.4 to 102.0 degrees Fahrenheit. **On 02 Nov 2020, her oxygen saturation was 92%.** On 04 Nov 2020, vital signs included oxygen saturation 96% and temperature 98.8 degrees Fahrenheit. The event, symptomatic COVID-19, was reported as resolved on 12 Nov 2020. Action taken with study drug was not applicable as the subject had already received both scheduled doses.

Subject ID	MCN
US3902015	(b) (6)
Preferred Term:	COVID-19
Treatment Assignment:	Placebo
Relationship	Not Related
Baseline SARS-CoV-2	Negative

This 53-year-old, black, female subject experienced the non-serious event of COVID-19. The subject's medical history was significant for morbid obesity. The subject received her first dose on 08 Sep 2020 and 2nd dose on 06 Oct 2020.

On 26 Oct 2020, the subject experienced COVID-19. From 26 Oct 2020 to 09 Nov 2020 the subject intermittently experienced mild to moderate symptoms of chills, cough, fatigue, body aches, nasal congestion, muscle aches, headache, runny nose, sore throat, shortness of breath, difficulty breathing, nausea and diarrhea. Subject denied new loss of taste, new loss of smell and vomiting. On 27 Oct 2020, treatment included naproxen sodium. On 28 Oct 2020, a SARS-CoV-2 real-time reverse transcription polymerase chain reaction nasopharyngeal swab was positive. Vital signs include pulse rate 95 beats/min, respiratory rate 16 breaths/min, blood pressure 122/70 mmHg and temperature 100.0 degrees Fahrenheit. Differential diagnosis was viral syndrome, caused by COVID-19. The subject was undergoing further evaluation by the primary care physician. The subject was an educator or student in the school setting, who resided in a single-family home (COVID-19 risk of exposure factors). On 29 Oct 2020, temperature was 102.4 degrees Fahrenheit. On 02 Nov 2020, treatment included acetaminophen/diphenhydramine hcl/phenylephrine hcl. On 04 Nov 2020, temperature was 98.5 degrees Fahrenheit and remained normal. **On 06 Nov 2020, oxygen saturation was 92%.** On 07 Nov 2020, oxygen saturation was 97% and remained normal. The event, COVID-19, was reported as resolving. Action taken with study drug was not applicable as the subject had already received both scheduled doses.